ATI-2021-001919

From January 1st, 2021 to December 31st, 2021, Health Canada's Canada Vigilance Program has received **670** fatal **domestic** adverse reaction (AR) reports with suspected **antipsychotic** products listed below; **12** of these deaths involved suicide.

"Amitriptyline, Abilify / Aripiprazole, Asenapine, Quetiapine, Cariprazine, Chlorpromazine, Zuclopenthixol, Clozapine, Flupentixol, Sulpiride, Fluphenazine, Haldol/haloperidol, Invega / paliperidone, Latuda / Lurasidone, Nozinan (Methotrimeprazine) / levomepromazine, Periciazine, Zyprexa / Olanzapine, Pimozide, Prochlorperazine, Periciazine, Promazine, Risperidone, Amisulpride, Trifluoperazine, desvenlafaxine".

From January 1st, 2021 to December 31st, 2021, Health Canada's Canada Vigilance Program has received **87** fatal **domestic** adverse reaction (AR) reports with suspected **antidepressant** products listed below.

"Citalopram, Escitalopram, Fluoxetine, Fluvoxamine, Paroxetine, Sertraline, Vortioxetine, Vilazodone, Duloxetine, Venlafaxine, Desvenlafaxine, Levomilnacipran, Amoxapine, Clomipramine, Desipramine, Doxepin, Imipramine, Nortriptyline, Protriptyline, Trimipramine, Mirtazapine, Bupropion, Trazodone, Trazodone, Vortioxetine, Vilazodone".

Please note the following caveats:

- It is often not possible to determine whether an adverse reaction reported to Health Canada is a result of using a specific health product. Other factors contributing to the reaction could be a person's health conditions or other health products they are using at the same time.
- Adverse reaction reports are suspected associations and reflect the opinion or observation of the individual reporter. The data do not reflect any Health Canada assessment of association between the health product and the reaction(s).
- Please consult the following <u>link</u> for additional caveats on the interpretation of suspected adverse reaction data collected by the Canada Vigilance program.

Page: 1 of/de 205 A2021001919



Search Criteria

Report Runtime:	2022-02-15 - 3:11 PM 1.82 minutes
Range for Initial Date Received	2021-01-01 to 2021-12-31
AER No(s)	
Country of Occurence	Domestic
Case Serious?	All
Case Outcome	Fatal
Report Source	All
Patient Gender	All
Range for Age (years)	All
Reporter Type	All
Source Company Unit	All
Product Role	
Product Class	All
Product Description	All
DIN/NPN	
	citalopram ESCITALOPRAM OXALATE Citalopram hydrochloride OXALATE D'ESCITALOPRAM citalopram hydrochloride citalopram hydrobromide CITALOPRAM citalopram as hydrobromide CITALOPRAM HYDROBROMIDE ESCITALOPRAM (OXALATE D') Escitalopram oxalate CITALOPRAM SALT NOT SPECIFIED escitalopram escitalopram oxalate CITALOPRAM HYDROCHLORIDE ESCITALOPRAM HYDROCHLORIDE Escitalopram Oxalate CITALOPRAM HYDROCHLORIDE Escitalopram Hydrobromide

CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement. (10/2007).



Glossary/Abbreviations

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Term	Definition	
Age	Age of the patient when the adverse reaction reports and age specific searches with the search of the adverse reaction reports and age specific search of the search of th	е
AR	Adverse Reaction CITALOPRAMUM Citalopram	
Gender	Gender of the patient as it was provided by পাৰি প্ৰতিবিশ্ব The gender is unknown in some of the ad reaction reports and gender specific seaforts আন্তঃ কিন্তু কিন	verse 1.
Health Product	A health product includes drugs and matter health product include both prescription and r prescription pharmaceuticals; biotech pology தூதியுத் அதி biologically-derived products such as vaccines, serums, and blood derived products; disinfectants; and radiopharmaceuticals.	ion-
Health Product Role	The characterization of the role of the Group Ray provided Deficient of the adverse reaction. The health product role representation of the individual reporter. Cause and effect relationships to the perfect of the health product reporter suspected the health product reporter suspected the health product reporter of the health product was not suspected by the representation of the health product at the time of the adverse reaction. The characterization of the adverse reporter of the adverse reaction of the adverse reaction.	that
HLT	High Level Term – see definition of MEUDRXETINE (CHLORHYDRATE DE)	
HLGT	High Level Group Term – see definition ល្អ Marking Maleate	
Initial Date of Receipt	The date that the first version of the adverse reaction report was received by Health Canada's Can fluvoxamine FLUVOXAMINE	ada
MedDRA	Medical Dictionary for Regulatory Activities and Industrial and internationally recognized standardize of terms used to facilitate the regulation of terms in a hierarchical structure whereby the preferred term of thigh level term (HLT). 'High level terms' are then grouped under the broader he of 'high level term' (HLT). 'High level terms' are then grouped under 'high level group terms (HLGT which are then grouped by 'system organ class' (SCC). The preferred term' is the most specific te the Summary of Reported Adverse Reactions while as system organ class' is the most general. paroxetine hydrochloride hemihydrate	tion
MedDRA Version	The MedDRA terminology is updated PAROXIETHNIS (CONTINUED CONTINUED CONTI	iyed
NEC	Not Elsewhere Classified – MedDRA abbreviation PAROXETINE HYDROCHLORIDE	
NOS	Not Otherwise Specified – MedDRA #Barewietione	
PT	paroxetine mesylate Preferred Term – A MedDRA Preferred Term – A MedDRA Preferred Term – A MedDRA Preferred Term investigation (single medical concept) for a symptom, sign disease, diagnosis, therapeutic indication investigate surgical or medical procedure, and medical social of family history characteristic PAROXETINE HYDROCHLORIDE HYDRATE	otor on,
Seriousness	The seriousness of the adverse reaction reported that required in-patient hospitalization reported that results in persistent of section of existing hospitalization, that causes continued in the considered a medically important and condition. The condition is considered a medically important and condition in the condition of existing hospitalization, that results in the condition of existing hospitalization, that results in the condition of existing hospitalization, that results in the condition of existing hospitalization, that causes condition of existing hospitalization, that results in the condition of existing hospitalization of e	ction genital
SOC	System Organ Class – A)

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sertraline hydrochloride SERTRALINE HYDROCHLORIDE Sertraline hydrochloride sertraline Sertraline Hydrochloride Sertraline SERTRALINE? SERTRALINE HYDROCHLORIDE Vortioxetine Vortioxetine hydrobromide VORTIOXETINE HYDROBROMIDE Vortioxetine Hydrobromide **VORTIOXETINE (BROMHYDRATE DE)** vortioxetine **VORTIOXETINE** vortioxetine hydrobromide vilazodone hydrochloride Vilazodone Hydrochloride Vilazodone vilazodone VILAZODONE Vilazodone hydrochloride VILAZODONE HYDROCHLORIDE Duloxetine duloxetine hydrochloride CHLORHYDRATE DE DULOXETINE Duloxetine Hydrochloride DULOXETINE (CHLORHYDRATE DE) duloxetine **DULOXETINE DULOXETINE HYDROCHLORIDE** Duloxetine hydrochloride venlafaxine DESVENLAFAXINE SUCCINATE MONOHYDRATE desvenlafaxine Desvenlafaxine Active Ingredient(s) densvenlafaxine succinate O-DESMETHYLVENLAFAXINE VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE VENLAFAXINE HCL Venlafaxine Desvenlafaxine succinate desvenlafaxine succinate venlafaxine hydrochloride desvenlafaxine succinate monohydrate **DESVENLAFAXINE** Venlafaxine hydrochloride VENLAFAXINE HYDROCHLORIDE Venlafaxine Hydrochloride Desvenlafaxine Succinate desvenlafaxine fumarate

\ / [max 1]
VENLAFAXINE
venlafaxine hcl
DESVENLAFAXINE SUCCINATE
LEVOMILNACIPRAN HYDROCHLORIDE
levomilnacipran
levomilnacipran hydrochloride
LEVOMILNACIPRAN
Levomilnacipran
Levomilnacipran hydrochloride
amoxapine
AMOXAPINE
Amoxapine
CLOMIPRAMINE
clomipramine hydrochloride CLOMIPRAMINE HYDROCHLORIDE
Clomipramine desmethylclomipramine
clomipramine
Clomipramine Hydrochloride
Desipramine
DESIPRAMINE
desipramine
desipramine hydrochloride
DESIPRAMINE HYDROCHLORIDE
doxepin hydrochloride
doxepin hcl
DOXEPIN HCL
DOXEPIN HYDROCHLORIDE
Doxepin
DOXEPIN
doxepin
trimipramine mesilate
Imipramine hydrochloride
IMIPRAMINE EMBONATE
Imipramine Hydrochloride
TRIMIPRAMINE MONOHYDROCHLORIDE
IMIPRAMINE PAMOATE
Trimipramine Maleate
trimipramine maleate
imipramine embonate
TRIMIPRAMINE MESILATE
imipramine
IMIPRAMINE HYDROCHLORIDE
TRIMIPRAMINE IMIPRAMINE
TRIMIPRAMINE MALEATE
Imipramine
trimipramine
imipramine hydrochloride
Trimipramine
THEOPERINIO

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-15 3:11 PMTotal Number of Reports:87Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: Al

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

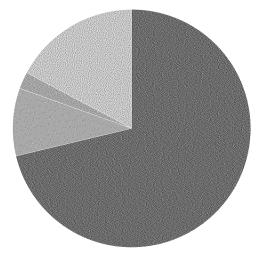
Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousn	ess
			Death	87
325	87 87	Ω7	Life Threatening	7
			Hospitalization required	14
		07	Disability	1
			Congenital Anomaly	0
			Other Medically	47

Age Group			
ADULT	62	71.26%	
ELDERLY	8	9.20%	
INFANT	2	2.30%	
UNKNOW N	15	17.24%	

	Patient Sex	
Female	35	40.23%
Male	49	56.32%
Not specified	2	2.30%
Unknown	1	1.15%



MedDRA Version:



M ADULT ■ ELDERLY ■ INFANT...

The Definition for age groups has been taken from the International Conference on Harmonization (ICH) and have been defined as follows:

- Neonate greater than zero and up to 27 days, inclusively
- Infant greater than 27 days and less than 2 years
- Child greater or equal to 2 and less than 12 years
- Adolescent greater or equal to 12 and less than 19 years
- Adult greater or equal to 19 and less than 65 years
- Elderly greater or equal to 65 years

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

MedDRA Version:

Report Runtime:2022-02-15 3:11 PMTotal Number of Reports:87Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All

System Organ Class	Number of All Reactions*	Reactions* (% of total)	Number of Reactions* where outcome of AR report was fatal
Cardiac disorders	23	7.08%	12
Congenital, familial and genetic disorders	1	0.31%	1
Gastrointestinal disorders	6	1.85%	4
General disorders and administration site conditions	55	16.92%	16
Hepatobiliary disorders	2	0.62%	1
Infections and infestations	9	2.77%	7
Injury, poisoning and procedural complications	72	22.15%	23
Investigations	29	8.92%	14
Metabolism and nutrition disorders	3	0.92%	2
Musculoskeletal and connective tissue disorders	2	0.62%	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.62%	1
Nervous system disorders	40	12.31%	17
Pregnancy, puerperium and perinatal conditions	2	0.62%	1
Psychiatric disorders	49	15.08%	12
Reproductive system and breast disorders	2	0.62%	1
Respiratory, thoracic and mediastinal disorders	15	4.62%	9
Skin and subcutaneous tissue disorders	1	0.31%	1
Social circumstances	4	1.23%	1
Surgical and medical procedures	3	0.92%	2
Vascular disorders	5	1.54%	4
Total Number of Reactions	325	100.00%	131

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



Canada Vigilance Summary of Product Adverse Reactions Santé Canada

MedDRA Version:

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87 Health Product: See Search Criteria All Age: Health Product Role: Gender: All

Seriousness:

Health

Canada

System Organ Class HLGT		Number of All Reactions*	Number of Reactions* where outcome	
HLT	PT	Neactions	of report was	
Cardiac disorders				
Cardiac arrhythmias				
Cardiac conduction disorders	Bundle branch block right	1	1	
	Arrhythmia	1	1	
Rate and rhythm disorders NEC	Bradycardia	1	1	
	Tachycardia	1	1	
Ventricular arrhythmias and cardiac arrest	Cardiac arrest	4	4	
	Cardio-respiratory arrest	5	5	
	Pulseless electrical activity	1	1	
	Ventricular arrhythmia	2	2	
Coronary artery disorders]		
Coronary artery disorders NEC	Arteriosclerosis coronary artery	3	3	
	Acute coronary syndrome	1	1	
Ischaemic coronary artery disorders	Myocardial infarction	1	1	
Myocardial disorders				
Myocardial disorders NEC	Left ventricular dysfunction	2	2	
		1		
	Cardiac disorders SOC Total	23	23	

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



Canada Vigilance Summary of Product Adverse Reactions Santé Canada

2022-02-15 3:11 PM Report Runtime: Total Number of Reports: 87 Health Product: See Search Criteria All Age: Health Product Role: Gender: All

Seriousness:	All	MedDRA V	ersion:		
Initial Date of Receipt:	2021-01-01 to 2021-12-31	Foreign or	Domestic:	Dome	stic
Congenital, familia	l and genetic disorders	S			
Neurological disorde	rs congenital				
Cerebral disorders	congenital	Anencephaly			1
	Congenital, familial a	nd genetic disorders SOC 1	otal	1	1
Gastrointestinal di	sorders				
Gastrointestinal mot	ility and defaecation conditi	ons			
Gastrointestinal at disorders NEC	onic and hypomotility	Intestinal pseudo-obstruction			1
Gastrointestinal sign	s and symptoms				
Na		Nausea	2	2	2
Nausea and vomit	ing symptoms	Vomiting		I	1
Peritoneal and retrop	peritoneal conditions				
Peritoneal and reti	roperitoneal disorders	Ascites	2	2	2
	Gastro	ointestinal disorders SOC 1	otal (5	6

Gastrointestinal disorders SOC Total	6	6

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

MedDRA Version:

1

1

1

1

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87 Health Product: See Search Criteria Αll Age: Health Product Role: Gender: All

Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Hanging

eneral disorders and administration site conditions			
Body temperature conditions			
Body temperature altered	Temperature regulation disorder	1	1
Febrile disorders	Pyrexia	1	1
Fatal outcomes			
	Accidental death	5	5
	Death	10	10
Death and sudden death	Death neonatal	1	1

General system disorders NEC			
	Asthenia	1	1
Asthenic conditions	Fatigue	2	2
	Malaise	4	4
General signs and symptoms NEC	Multiple organ dysfunction syndrome	1	1
Oedema NEC	Oedema	1	1

Sudden cardiac death

nerapeutic and nontherapeutic ef	rects (exci toxicity)		
	Drug interaction	21	21
I-4	Food interaction	2	2
Interactions	Potentiating drug interaction	2	2
	Tobacco interaction	1	1

General disorders and administration site conditions SOC Total	55	55
----------------------------------------------------------------	----	----

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87 Health Product: See Search Criteria Age: ΑII Health Product Role: All Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Hepatobiliary disorders Hepatic and hepatobiliary disorders 2 2 Hepatic fibrosis and cirrhosis Hepatic cirrhosis 2 **Hepatobiliary disorders SOC Total** 2 Infections and infestations **Bacterial infectious disorders** Bacterial infections NEC 1 1 Stenotrophomonas infection 1 Staphylococcal infections 1 Staphylococcal infection Infections - pathogen unspecified 3 3 Pneumonia Lower respiratory tract and lung 1 1 infections Pneumonia aspiration 1 1 Pneumonia necrotising 1 1 Bacteraemia Sepsis, bacteraemia, viraemia and fungaemia NEC 1 1 Sepsis Infections and infestations SOC Total 9 9 Injury, poisoning and procedural complications Bone and joint injuries 1 Pelvic fractures and dislocations Pelvic fracture Exposures, chemical injuries and poisoning

Exposures associated with pregnancy,

delivery and lactation



1

1

Exposure during pregnancy

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:

Health

Canada

2022-02-15 3:11 PM

Total Number of Reports:

Health Product:

See Search Criteria

Age:

87 All All

Health Product Role:

MedDRA Version:

Gender:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic:

Domestic

Exposures associated with pregnancy, delivery and lactation	Maternal exposure during pregnancy	2	2
Deiensian and toxicit.	Poisoning	3	3
Poisoning and toxicity	Toxicity to various agents	20	20

Injuries by physical agents			
Heat injuries (excl thermal burns)	Heat stroke	1	1

Injuries NEC			
Abdominal and gastrointestinal injuries NEC	Abdominal injury	1	1
Cerebral injuries NEC	Brain herniation	3	3
New site and sife injuries NEC	Fall	3	3
Non-site specific injuries NEC	Road traffic accident	1	1
Site specific injuries NEC	Head injury	1	1

ledication errors and other product use error	s and issues		
Medication errors, product use errors and issues NEC	Product use in unapproved indication	3	3
	Accidental overdose	2	2
	Failure to suspend medication	2	2
Product administration errors and issues	Incorrect route of product administration	1	1
	Wrong patient received product	2	2
Product monitoring errors and issues	Labelled drug-drug interaction issue	3	3

Off label uses and intentional product mis	suses/use issues		
Intentional product misuses	Intentional product misuse	1	1
Intentional product use issues	Intentional product use issue	2	2
Off label uses	Off label use	3	3

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 3:11 PM Health Product:

Total Number of Reports: Age:

87 All

All

Health Product Role:

See Search Criteria

Gender: MedDRA Version:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31 Foreign or Domestic:

Domestic

Overdoses and underdoses NEC			
	Intentional overdose	1	1
Overdoses NEC	Overdose	13	13
	Prescribed overdose	2	2

Injury, poisoning and procedural complication	ns SOC Total 72	72
-----------------------------------------------	-----------------	----

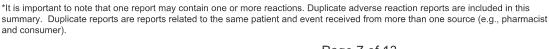
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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

2022-02-15 3:11 PM Report Runtime: Total Number of Reports: Health Product: See Search Criteria All Age: Health Product Role: Gender: All MedDRA Version: Seriousness: All

nitial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Do		stic: Domestic	
vestigations			
Cardiac and vascular investigations (excl enz	zyme tests)		
ECG investigations	Electrocardiogram QT prolonged	3	3
Investigations, imaging and histopathology p	procedures NEC		I
Imaging procedures NEC	X-ray	1	1
Protein and chemistry analyses NEC			
Chemistry analyses NEC	Serum serotonin increased	1	1
Toxicology and therapeutic drug monitoring			
	Analgesic drug level above therapeutic	1	1
Therapeutic drug monitoring analyses	Antidepressant drug level above therapeutic	3	3
	Benzodiazepine drug level therapeutic	1	1
	Alcohol test positive	2	2
	Amphetamines positive	1	1
	Blood ethanol increased	1	1
	Opiates positive	5	5
Toxicology laboratory analyses	Postmortem blood drug level	2	2
	Postmortem blood drug level abnormal	2	2
	Postmortem blood drug level increased	3	3
	Toxicologic test abnormal	3	3
	luuratinatina 200 Tatal	00	00

Investigations SOC Total	29	29
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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

2022-02-15 3:11 PM Total Number of Reports: Report Runtime: Health Product: See Search Criteria Age: ΑII Health Product Role: Αll Gender: MedDRA Version: Seriousness: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Metabolism and nutrition disorders Acid-base disorders Metabolic acidoses (excl diabetic 1 acidoses) Metabolic acidosis 1 Appetite and general nutritional disorders 2 2 Appetite disorders Decreased appetite Metabolism and nutrition disorders SOC Total 3 3 Musculoskeletal and connective tissue disorders Musculoskeletal and connective tissue disorders NEC 1 1 Back pain Musculoskeletal and connective tissue pain and discomfort 1 1 Pain in extremity Musculoskeletal and connective tissue disorders SOC Total 2 2 Neoplasms benign, malignant and unspecified (incl cysts and polyps) Hepatobiliary neoplasms malignant and unspecified 2 2 Hepatic neoplasms malignant Hepatic cancer ms benign, malignant and unspecified (incl cysts and polyps) SOC Total 2 2 **Nervous system disorders** Central nervous system vascular disorders 1 1 Haemorrhage intracranial Central nervous system haemorrhages and cerebrovascular accidents 2 2 Ischaemic cerebral infarction

Encephalopathies

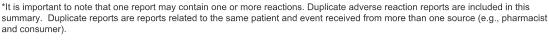


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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:	2022-02-15 3:11 PM	Tota	al Number of Reports:	87	
Health Product:	See Search Criteria	Age	:	All	
Health Product Role:		Gen	nder:	All	
Seriousness:	All	Med	IDRA Version:		
Initial Date of Receipt:	2021-01-01 to 2021-12-31	Fore	eign or Domestic:	Dome	stic
Encephalopathies f	NEC	Hypoxic-ischaemic encephalopathy	2		2
Headaches					
Headaches NEC		Headache	1		1
Increased intracranial	pressure and hydrocephal	us			
Increased intracran	ial pressure disorders	Brain oedema	2		2
Mental impairment dis	sorders				
Mental impairment memory loss)	(excl dementia and	Mental impairment	2		2
	NEC				
Neurological disorder	'S NEC				
Coma states		Coma	1		1
		Depressed level of conscio	usness 1		1
Disturbances in cor	nsciousness NEC	Loss of consciousness	3		3
		Somnolence	4		4
Nourological signs	and symptoms NEC	Dizziness	7		7
rveurological signs	and symptoms NEO	Unresponsive to stimuli	7		7
Paraesthesias and	dysaesthesias	Burning sensation	1		1
Speech and langua	ge abnormalities	Speech disorder	1		11
Neuromuscular disore	ders				
Muscle tone abnorr	mal	Serotonin syndrome	2		2
Seizures (incl subtype	es)				
Seizures and seizu	re disorders NEC	Status epilepticus	2		2

Structural brain disorders





Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87 Health Product: See Search Criteria Age: ΑII Health Product Role: All Gender: MedDRA Version: Seriousness: Foreign or Domestic: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Domestic 1 1 Structural brain disorders NEC Brain injury **Nervous system disorders SOC Total** 40 40 Pregnancy, puerperium and perinatal conditions Abortions and stillbirth Stillbirth and foetal death 2 2 Foetal death 2 2 Pregnancy, puerperium and perinatal conditions SOC Total **Psychiatric disorders** Anxiety disorders and symptoms 1 1 Anxiety symptoms Anxiety Deliria (incl confusion) Confusion and disorientation 4 4 Confusional state Depressed mood disorders and disturbances 16 Depressive disorders 16 Depression Psychiatric and behavioural symptoms NEC 1 1 Psychiatric symptoms NEC Psychiatric decompensation Psychiatric disorders NEC 2 Mental disorders NEC Mental disorder 2 13 13 Drug abuse Substance related and addictive disorders

Sleep disorders and disturbances

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3

3

Drug dependence

2

2

Canada Vigilance Summary of Product Adverse Reactions

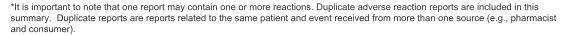
Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: Health Product: See Search Criteria Αll Age: Health Product Role: Gender: All Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Disturbances in initiating and maintaining 1 1 Insomnia Sleep disorders NEC 1 1 Sleep disorder Suicidal and self-injurious behaviours NEC Completed suicide 5 5 1 1 Suicidal and self-injurious behaviour Suicidal ideation 1 1 Suicide attempt **Psychiatric disorders SOC Total** 49 49 Reproductive system and breast disorders Prostatic disorders (excl infections and inflammations) Prostatic neoplasms and hypertrophy 2 2 Benign prostatic hyperplasia

Reproductive system and breast disorders SOC Total

*It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this
summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist
and consumer).

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87 Health Product: See Search Criteria Age: All Health Product Role: Αll Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Respiratory, thoracic and mediastinal disorders Bronchial disorders (excl neoplasms) 2 2 Asthma Bronchospasm and obstruction 1 1 Wheezing Lower respiratory tract disorders (excl obstruction and infection) Lower respiratory tract inflammatory and 2 2 immunologic conditions Pneumonitis 2 2 Pulmonary oedemas Pulmonary congestion Pulmonary vascular disorders Pulmonary thrombotic and embolic 2 2 conditions Pulmonary embolism Respiratory disorders NEC Breathing abnormalities 2 2 Respiratory depression 2 2 Asphyxia Conditions associated with abnormal gas exchange 1 1 Нурохіа Respiratory tract signs and symptoms Upper respiratory tract signs and symptoms Oropharyngeal pain 1 1 Respiratory, thoracic and mediastinal disorders SOC Total 15 15 Skin and subcutaneous tissue disorders Angioedema and urticaria Angioedemas 1 1 Angioedema



Skin and subcutaneous tissue disorders SOC Total



1

1

Health

Canada

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87 Health Product: See Search Criteria Age: Αll Health Product Role: Αll Gender: Seriousness: MedDRA Version: Foreign or Domestic: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Domestic Social circumstances Lifestyle issues Loss of personal independence in Disability issues 4 4 daily activities Social circumstances SOC Total 4 4 Surgical and medical procedures Gastrointestinal therapeutic procedures 1 1 Abdominal therapeutic procedures NEC Laparotomy Therapeutic procedures and supportive care NEC Therapeutic procedures NEC 2 2 Therapy change Surgical and medical procedures SOC Total 3 3 Vascular disorders Decreased and nonspecific blood pressure disorders and shock 1 Circulatory collapse and shock Shock 1 2 2 Vascular hypotensive disorders Hypotension **Embolism and thrombosis** Peripheral embolism and thrombosis 1 1 Deep vein thrombosis Vascular disorders NEC 1 1 Site specific vascular disorders NEC Pallor 5 Vascular disorders SOC Total 5

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).





Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

				2007					2021							Part of the second
		Jani	uary	Febr	uary	Mai	rch	Ar	oril	Ma	ıy	Ju	ne	Ju	ily	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Acute coronary syndrome		1													
	Arrhythmia															
	Arteriosclerosis coronary artery	5-1)) 				G.			Q.,	
	Bradycardia									1	1					
	Bundle branch block right	F55			85-	925	1,									
One the discoulant	Cardiac arrest					1	1			1	1					
Cardiac disorders	Cardio-respiratory arrest															<u> </u>
	Left ventricular dysfunction															
	Myocardial infarction	1								Z		1,1	1			Z
	Pulseless electrical activity									1	1					
	Tachycardia			ر				ر. ماندانداندانداندانداندانداندانداندانداندا			ر میں استعماد دارا۔ اس دامیں استعماد دارا۔		2			
	Ventricular arrhythmia															1
	SOC Subtotal	2	2	1	1	3	3			3	3	1	1			1
Congenital, familial and genetic disorders	Anencephaly															· 1
	SOC Subtotal															1

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

						20)21	3 30 30 30				
			Septe	mber	Oct	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Acute coronary syndrome										1	1
	Arrhythmia						1	1			1	1
	Arteriosclerosis coronary artery		1	_1							3	3
	Bradycardia										1	1
	Bundle branch block right						987			227	1	1
	Cardiac arrest				1	1			1	1	4	4
Cardiac disorders	Cardio-respiratory arrest				4	4		(J., 1,	A	2	5	5
	Left ventricular dysfunction				1	1			1	1	2	2
	Myocardial infarction				Z						1	1
	Pulseless electrical activity										1	1
	Tachycardia] ************************************	ر. بر						,		1	1
	Ventricular arrhythmia	1							1	1	2	2
	SOC Subtotal	1	1	1	6	6	2	2	3	3	23	23
Congenital, familial and genetic disorders	Anencephaly	11									1	1
	SOC Subtotal	1									1	1



Seriousness:

Canada Vigilance Summary of Product Adverse Reactions

Gender:

MedDRA Version:

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports:
Health Product: See Search Criteria Age:

Health Product Role:

All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

								170	2021							
		Jan	uary	Febr	uary	Mai	rch	Ap	ril	м	ау	Ju	ne	Ju	ıly	August
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Ascites							1	1							
Gastrointestinal	Intestinal pseudo- obstruction		567			1	1									
disorders	Nausea															
	Vomiting													5		
A Parameter Company	SOC Subtotal					1	1	1	1							
	Accidental death									1	1					1
	Asthenia															
	Death	1	1	1	1	2	2							2	2	1
General disorders and administration site conditions	Death neonatal															
	Drug interaction			5	5			2	2	2	2	4	4			2
	Fatigue															
	Food interaction															1

87

All

ΑII



September

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

Total Number of Reports: 87

Age: All

Gender: All

October

Health Product Role:

MedDRA Version:

2021

Seriousness: All

E : B : :

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

November

December

			Jopie			,						
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Ascites								1	1	2	2
Gastrointestinal	Intestinal pseudo- obstruction										1	1
disorders	Nausea		1	1					1	1	2	2
	Vomiting									1	1	1
	SOC Subtotal		1	1					3	3	6	6
	Accidental death	1					2	2	1	1	5	5
	Asthenia										1	1
	Death	1					1	1	2	2	10	10
General disorders and administration site conditions	Death neonatal										1	1
	Drug interaction	2	2	2	1	1	1	1	2	2	21	21
	Fatigue										2	2
	Food interaction	1							1	1	2	2
			-	-		Poo	e 4 of 24	1				



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Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

Total Number of Reports: 87
Age: All

Health Product Role:

Gender: All

Seriousness: All

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

								-2-	2021							
		Jan	uary	Febr	uary	Ma	rch	Aŗ	oril	М	ay	Ju	ne	Ju	ily	August
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Hanging						1									
	Malaise					1	1									1
	Multiple organ dysfunction syndrome															
	Oedema															
General disorders and administration site conditions	Potentiating drug interaction															
	Pyrexia					1	1									
	Sudden cardiac death															
	Temperature regulation disorder			1	1											
	Tobacco interaction															
	SOC Subtotal	1	1	7	7	8	8	2	2	3	3	4	4	2	2	7



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Report Runtime: 2022-02-15 3:11 PM

All

Total Number of Reports: 87

Health Product: See Search Criteria

Age: All Gender: All

Health Product Role:

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

				3557		20	121		The second second			
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Hanging										1	1
	Malaise	1					1	1	1	1	4	4
	Multiple organ dysfunction syndrome										1	1
	Oedema						1	1			1	1
General disorders and administration site conditions	Potentiating drug interaction										2	2
	Pyrexia										1	1
	Sudden cardiac death										1	1
	Temperature regulation disorder										1	1
	Tobacco interaction										1	1
	SOC Subtotal	7	3	3	1	1	7	7	10	10	55	55



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Rec	eipt: 2021-01-01 to	2021-12-3	l		Fore	eign or Dor	nestic:	D(omestic							
									2021							
		Jan	uary	Febr	uary	Mai	rch	Ap	ril	M	ау	Ju	ne	Ju	ly	August
SOC	PT PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
lepatobiliary disorders	Hepatic cirrhosis							1	1							
	SOC Subtotal							1	1							
	Bacteraemia					:: :-::: 1						11				
	Pneumonia					1	1									1
	Pneumonia aspiration			/	2	2	2							7		
nfections and nfestations	Pneumonia necrotising											1	1			
	Sepsis					21	2 1		7 7 7	/			/	7		2
	Staphylococcal infection					1	1									
	Stenotrophomonas infection			7		2 1						7 Tanana		7		
	SOC Subtotal					5	5					2	2			1
	Abdominal injury															
njury, poisoning and procedural complications	Accidental overdose															
	Brain herniation							1	1				<u> </u>			



Health Product:

Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

MedDRA Version:

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports:

See Search Criteria Age:
Gender:

Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

						20	21	9 00 00 00				
			Septe	ember	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcom Fatal
Hepatobiliary disorders	Hepatic cirrhosis								1	1	2	2
	SOC Subtotal								1	1	2	2
	Bacteraemia				1: 2:						1	1
	Pneumonia	1							1	74	3	3
	Pneumonia aspiration								7		1	1
nfections and nfestations	Pneumonia necrotising										1	1
	Sepsis			2			7		/		1	1
	Staphylococcal infection										1	1
	Stenotrophomonas infection			7			7 Table 1				1	1
	SOC Subtotal	1							1	1	9	9
	Abdominal injury						1	1			1	1
njury, poisoning and procedural omplications	Accidental overdose										2	2
	Brain herniation		1	1		11. 2. 21.11.11			1	1	3	3

87

All

All



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

							100	100	2021							
		Jan	uary	Febr	uary	Ma	rch	Ар	oril	Ma	зу	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Exposure during pregnancy															
	Failure to suspend medication									1	1					
	Fall					1										
	Head injury															
Injury, poisoning and procedural	Heat stroke			i												
complications	Incorrect route of product administration															
	Intentional overdose			1	1											
	Intentional product misuse															
	Intentional product use issue										1					
	Labelled drug-drug interaction issue															1



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Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

All

Total Number of Reports: 87
Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

				100.00		20	21					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Exposure during pregnancy		1	1							1	1
	Failure to suspend medication						1	1			2	2
	Fall										3	3
	Head injury		1	1							1	1
Injury, poisoning and procedural	Heat stroke										1	1
complications	Incorrect route of product administration				1	1					1	1
	Intentional overdose										1	1
	Intentional product misuse						1	1			1	1
	Intentional product use issue		1	1							2	2
	Labelled drug-drug interaction issue	1					1	1	1	1	3	3



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

Total Number of Reports: 87
Age: All

Health Product Role:

Gender: All

Seriousness: All

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

									2021							
		Jan	uary	Febr	uary	Ma	rch	Ар	oril	May		June		July		August
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Maternal exposure during pregnancy															1
	Off label use	1	1					1	1							
	Overdose															
	Pelvic fracture															
Injury, poisoning and procedural	Poisoning															
complications	Prescribed overdose									1	1					
	Product use in unapproved indication	1	1													
	Road traffic accident															
	Toxicity to various agents		1			2	2			11		3	3			
	Wrong patient received product									1	1					
	SOC Subtotal	3	3	4	4	3	3	2	2	6	6	4	4	1	1	2



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

All

Total Number of Reports: 87
Age: All

Health Product Role:

Gender: MedDRA Version:

Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

All

				2021										
SOC			Septe	mber	Oct	ober	Nove	mber	December					
	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal		
	Maternal exposure during pregnancy	1	1								2	2		
	Off label use								1	1	3	3		
	Overdose		1		5	5	1	1	4	4	13	13		
	Pelvic fracture						1	1			1	1		
Injury, poisoning and procedural	Poisoning				1	1	ź	2			3	3		
complications	Prescribed overdose		1	1							2	2		
	Product use in unapproved indication					1	1	1			3	3		
	Road traffic accident						1	1			1	1		
	Toxicity to various agents				5	5	3	3	3	3	20	20		
	Wrong patient received product						1	1			2	2		
	SOC Subtotal	2	8	8	14	14	15	15	10	10	72	72		



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

		2021														
		January		Febr	February		March		April		May		June		July	
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Alcohol test positive			1/21/201	111							1	1			
	Amphetamines positive							<u> </u>				1	1			
	Analgesic drug level above therapeutic					2		7. 7.		7. 7.						
	Antidepressant drug level above therapeutic															1
	Benzodiazepine drug level therapeutic								7			1	1			
	Blood ethanol increased											1	1			
Investigations	Electrocardiogram QT prolonged		5						7	7	2000	773			7.7	21
	Opiates positive			1	1							3	3			
	Postmortem blood drug level															1
	Postmortem blood drug level abnormal															
	Postmortem blood drug level increased			1		11	1017					2	2			
	Serum serotonin increased									1	1					
	Toxicologic test abnormal			1								jene.	1-1-1			
	X-ray			**************************************		1	1							A CONTRACTOR OF THE PARTY OF TH	***************************************	
	SOC Subtotal			3	3	2	2			1	1	10	10			3



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime:2022-02-15 3:11 PMTotal Number of Reports:87Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

				2021										
			Septe	ember	Octol		November		December					
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal		
	Alcohol test positive										2	2		
	Amphetamines positive										1	1		
	Analgesic drug level above therapeutic		Ć.					2000	2 1	2 1	1	1		
	Antidepressant drug level above therapeutic	1							2	2	3	3		
	Benzodiazepine drug level therapeutic							2 Table 1	7 7	20.	1	1		
	Blood ethanol increased										1	1		
Investigations	Electrocardiogram QT prolonged	2							2	2	3	3		
	Opiates positive								1	1	5	5		
	Postmortem blood drug level									375	2	2		
	Postmortem blood drug level abnormal		1	1	1	1					2	2		
	Postmortem blood drug level increased						Pego.				3	3		
	Serum serotonin increased										1	1		
	Toxicologic test abnormal								25152		3	3		
	X-ray		- All All All All All All All All All Al		,		1				1	1		
	SOC Subtotal	3	1	1	1	1			8	8	29	29		



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

initial Date of Rec	elpt: 2021-01-011	.0 2021-12-3	ı		Fore	eign or Doi	mesuc:	יט	omestic		~					
		2021														
			January		February		March		April		May		June		July	
soc	PT	All Reactions	Outcome Fatal	All Reactions												
Metabolism and nutrition disorders	Decreased appetite						1									
	Metabolic acidosis		:	1	1											
	SOC Subtotal			1	1	1	1									
Musculoskeletal and connective tissue	Back pain					25								365		
disorders	Pain in extremity															
	SOC Subtotal															
eoplasms benign, nalignant and nspecified (incl cysts nd polyps)	Hepatic cancer															
	SOC Subtotal					1	1							1	1	··
	Brain injury									1	1					
Nervous system	Brain oedema							\$2 1	- 1							
disorders	Burning sensation															
	Coma															



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: Health Product: See Search Criteria Age:

Health Product Role:

ΑII

Seriousness: Initial Date of Receipt: 2021-01-01 to 2021-12-31 87

All Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

			2021									
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Metabolism and	Decreased appetite								1	1	2	2
nutrition disorders	Metabolic acidosis										1	1
	SOC Subtotal								1	1	3	3
Musculoskeletal and	Back pain			5.5.1							1	1
onnective tissue isorders	Pain in extremity				1	1					1	1
	SOC Subtotal		1	1	1	1					2	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hepatic cancer										2	2
	SOC Subtotal								- Control of the cont		2	2
	Brain injury										1	1
Nervous system	Brain oedema								55. 1	2.1	2	2
disorders	Burning sensation				1	1					1	1
	Coma		/ 1	1							1	1



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87
Health Product: See Search Criteria Age: All

Health Product Role: Gender:
Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		2021														
		Jan	uary	Febr	uary	Ma	rch	Aŗ	oril	М	ay	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Depressed level of consciousness											1	1			
	Dizziness					4	4									
	Haemorrhage intracranial															
	Headache															
	Hypoxic-ischaemic encephalopathy															
	Ischaemic cerebral infarction							1	1							
Nervous system disorders	Loss of consciousness									1	1	1	1			
	Mental impairment															50 1
	Serotonin syndrome							1	1							
	Somnolence			1	1											1
	Speech disorder			1	1											
	Status epilepticus															
	Unresponsive to stimuli					4	4									
	SOC Subtotal			2	2	8	8	3	3	2	2	2	2			2

ΑII



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports:
Health Product: See Search Criteria Age:

Age: All Gender: All

Health Product Role:

MedDRA Version:

Seriousness: All Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

87

			2021									
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Depressed level of consciousness										1	1
	Dizziness						3	3			7	7
	Haemorrhage intracranial		1	1							1	1
	Headache										1	1
	Hypoxic-ischaemic encephalopathy				1	1			1	1	2	2
	Ischaemic cerebral infarction								571	51	2	2
Nervous system disorders	Loss of consciousness								1	1	3	3
	Mental impairment	1							1	1	2	2
	Serotonin syndrome								1	1	2	2
	Somnolence	#1 #1					1	51	1	1	4	4
	Speech disorder										1	1
	Status epilepticus				545	1			1	1	2	2
	Unresponsive to stimuli						2	2	1	1	7	7
	SOC Subtotal	2	3	3	3	3	6	6	9	9	40	40



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: 87
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

									2021						Section 1	
		Janı	uary	Febr	uary	Ma	rch	A	pril	М	ау	Ju	ne	Jı	uly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
Pregnancy, puerperium and perinatal conditions	Foetal death															
	SOC Subtotal										100					
	1		L			1	1	L	L	1	1	1	L	L		
	Anxiety															
	Completed suicide			2	2		().t ;									
	Confusional state	1		1	1											1
	Depression			1::4:	4			22	2	1::1	1::1:	4	4			1
	Drug abuse			1	1	1	1					1	1	1	1	Market Market
	Drug dependence		7													
Psychiatric disorders	Insomnia			1.29,22000		Property of the second				1,24,1,2					The section of the se	in some grown
	Mental disorder							1	1::1:							
	Psychiatric decompensation									1	1					
	Sleep disorder	1,	2													
	Suicidal ideation	1														
	Suicide attempt															
	SOC Subtotal			8	8	2	2	3	3	2	2	5	5	1	1	2
					T	T	T	T		1					1	
Reproductive system and breast disorders	Benign prostatic hyperplasia					1	1							1	1	
	SOC Subtotal					1	1							1	1	



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Report Runtime: 2022-02-15 3:11 PM Total Number of Reports: Health Product: See Search Criteria Age:

Health Product Role:

ΑII Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 87

All Gender: ΑII

MedDRA Version:

Foreign or Domestic: Domestic

						20)21					
			Septe	ember	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Pregnancy, puerperium and perinatal conditions	Foetal death		-2	2							2	2
	SOC Subtotal		2	2							2	2
	Anxiety						1	1			1	1
	Completed suicide				<u> </u>	1		1			5	5
	Confusional state	1	1	1			1.2		1	1	4	4
	Depression	1 ,	2	2	1	1 1	1	1		7	16	16
	Drug abuse		· · · · · · · · · · · · · · · · · · ·		5	5	4	4			13	13
	Drug dependence				<u> </u>		3.15	1.1	2	2	3	3
Psychiatric disorders	Insomnia				- Information -		1	1			1	1
	Mental disorder						11	1,		1	2	2
	Psychiatric decompensation										1	1
	Sleep disorder	1								1	1	1
	Suicidal ideation				1	1					1	1
	Suicide attempt				1	1,			1		1	1
	SOC Subtotal	2	3	3	9	9	10	10	4	4	49	49
Reproductive system and breast disorders	Benign prostatic hyperplasia										2	2
	SOC Subtotal										2	2



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Report Runtime: 2022-02-15 3:11 PM Total Number of Reports:
Health Product: See Search Criteria Age:

Health Product Role: Gender:
Seriousness: All MedDRA Version:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		2021														
		Jan	uary	Febr	ruary	Mai	rch	A	oril	М	ay	Ju	ne	Ju	ly	August
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Asphyxia				1											
	Asthma					1	1							1	1	
	Нурохіа															
	Oropharyngeal pain															
Respiratory, thoracic and mediastinal disorders	Pneumonitis															
	Pulmonary congestion															
	Pulmonary embolism															
	Respiratory depression															1
	Wheezing						1									
	SOC Subtotal			1	1	4	4			1	1			1	1	1

87

All

ΑII



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Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

Total Number of Reports: 87
Age: All
Gender: All

Health Product Role:

MedDRA Version:

Seriousness: All

- · - -

Initial Date of Receipt:

2021-01-01 to 2021-12-31 Foreign

Foreign or Domestic: Domestic

			2021									
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Asphyxia		1	1							2	2
	Asthma										2	2
	Hypoxia										1	1
	Oropharyngeal pain								1	1	1	1
Respiratory, thoracic and mediastinal disorders	Pneumonitis				1-2					1	2	2
	Pulmonary congestion						1	1	1	1	2	2
	Pulmonary embolism										2	2
	Respiratory depression	1							1	1	2	2
	Wheezing										1	1
	SOC Subtotal	1	1	1	1	1	1	1	4	4	15	15



Report Runtime:

Canada Vigilance Summary of Product Adverse Reactions

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Health Product: All See Search Criteria Age: Gender: ΑII Health Product Role:

Seriousness: All MedDRA Version:

2022-02-15 3:11 PM

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

									2021							
		Jan	uary	Febr	uary	Ma	rch	Ар	ril	M	ay	Ju	ne	Ju	ily	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
Skin and subcutaneous issue disorders	Angioedema					1	1									
	SOC Subtotal					1	1									
Social circumstances	Loss of personal independence in daily activities									251			577			
	SOC Subtotal									1	1					
urgical and medical	Laparotomy					1	1									
rocedures	Therapy change	:						Z		<u></u>	1					
	SOC Subtotal					1	1			1	1					
	Deep vein thrombosis									1	1					
/ascular disorders	Hypotension						5.15		<i></i>	535	(1)					
accara, arcoració	Pallor					1	1									
	Shock			1 1	1			2 · · · · · · · · · · · · · · · · · · ·	2000	*						
	SOC Subtotal			1	1	2	2			2	2					
	Grand Total	6	6	28	28	43	43	12	12	22	22	28	28	7	7	20

Total Number of Reports:

87

Canada

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM Health Product: See Search Criteria

All

All Age: Gender: All

Total Number of Reports:

Health Product Role:

MedDRA Version:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

87

		2021										
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcom Fatal
Skin and subcutaneous tissue disorders	Angioedema										1	1
	SOC Subtotal										1	1
Social circumstances	Loss of personal independence in daily activities			57.J					32	5,7	4	4
	SOC Subtotal		1	1	1	1	1	1			4	4
Surgical and medical	Laparotomy										1	1
procedures	Therapy change		·		1	1		j.		\$	2	2
	SOC Subtotal				1	1					3	3
	Deep vein thrombosis										1	1
Vascular disorders	Hypotension								3.5	533	2	2
vasculai disorders	Pallor										1	1
	Shock										1	1
	SOC Subtotal										5	5
	Grand Total	20	25	25	38	38	42	42	54	54	325	325

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l'information par Santé Canada



Report Runtime: 2022-02-15 3:11 PM Health Product: See Search Criteria

Total Number of Reports: 87 All Age: ΑII

Health Product Role:

Gender:

All Seriousness:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		20	21	(0)(0) (1)	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Acute coronary syndrome	1	1 2 - 1	1	1
	Arrhythmia	1	1	1	1
	Arteriosclerosis coronary artery	3	3	3	3
	Bradycardia	1	1	1	1
	Bundle branch block right		[] []	1	1
Cardiac disorders	Cardiac arrest	4	4	4	4
Cardiac disorders	Cardio-respiratory arrest	5	5	5	5
	Left ventricular dysfunction	2	2	2	2
	Myocardial infarction	1	1,500	1	1
	Pulseless electrical activity	1	1	1	1
	Tachycardia	1	1	1	1
	Ventricular arrhythmia	2	2	2	2
200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 -	SOC Subtotal	23	23	23	23
Congenital, familial and genetic disorders	Anencephaly	1		1	4
	SOC Subtotal	1	1	1	1



Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

Total Number of Reports: 87
Age: All

Health Product Role:

Gender: All

Seriousness: All

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	21	0.050 0.050	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Ascites	2	2	2	2
Gastrointestinal	Intestinal pseudo- obstruction	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	5 1	1	1
disorders	Nausea	2	2	2	2
	Vomiting			1	1
	SOC Subtotal	6	6	6	6
	Accidental death	5	5	5	5
	Asthenia			1	1
	Death	10	10	10	10
General disorders	Death neonatal	1		1	1
site conditions	Drug interaction	21	21	21	21
	Fatigue	2	2	2	2
	Food interaction	2	2	2	2
	Hanging	1		1	1



Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

All

Age: All Gender: All

Health Product Role:

Gender: MedDRA Version:

Total Number of Reports:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

87

		20	21	(6.00 pt.)	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Malaise	4	4	4	4
	Multiple organ dysfunction syndrome	1	1	1	1
	Oedema	1	1	1	1
General disorders and administration	Potentiating drug interaction	2	2	2	2
site conditions	Pyrexia	1	1	1	1
	Sudden cardiac death	1	1	1	1
	Temperature regulation disorder	1	1	1	1
	Tobacco interaction	1 1	1 1	1	1
	SOC Subtotal	55	55	55	55
Hepatobiliary disorders	Hepatic cirrhosis	2	2	2	2
	SOC Subtotal	2	2	2	2



Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

All

Total Number of Reports: 87
Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		2021		0.00	100 miles
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Bacteraemia	1	1	1	1
	Pneumonia	3	3	3	3
	Pneumonia aspiration	1 1	1 2-1 2-1-2-1	1	1
Infections and infestations	Pneumonia necrotising	1	1	1	1
	Sepsis	12.5	56 1 /6	1	1
	Staphylococcal infection	1	1	1	1
	Stenotrophomonas infection	(1		1	1
	SOC Subtotal	9	9	9	9
	Abdominal injury	1	1	1	1
	Accidental overdose	2	2	2	2
Injury, poisoning and procedural complications	Brain herniation	3	3	3	3
	Exposure during pregnancy	1		1	1
	Failure to suspend medication	2	2	2	2



Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

All

Total Number of Reports: 87
Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		2021		600	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Fall	3	3	3	3
	Head injury	1	1	1	4
	Heat stroke	1	1	1	1
	Incorrect route of product administration	1	1	1	1
	Intentional overdose	1		1	1
Injury, poisoning and procedural complications	Intentional product misuse	1	1	1	1
	Intentional product use issue	2	2	2	2
	Labelled drug-drug interaction issue	3	3	3	3
	Maternal exposure during pregnancy	2	2	2	2
	Off label use	3	3	3	3
	Overdose	13	13	13	13

A2021001919



Report Runtime: 2022-02-15 3:11 PM Health Product: See Search Criteria

All

All Age: Gender: ΑII

Health Product Role:

Initial Date of Receipt:

Seriousness:

2021-01-01 to 2021-12-31

MedDRA Version:

Total Number of Reports:

Foreign or Domestic: Domestic

87

		2021		5515	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Pelvic fracture	1	1	1	1
	Poisoning	3	3	3	3
	Prescribed overdose	2	2	2	2
Injury, poisoning and procedural complications	Product use in unapproved indication	3	3	3	3
	Road traffic accident	1	1	1	1
	Toxicity to various agents	20	20	20	20
	Wrong patient received product	2	2	2	2
	SOC Subtotal	72	72	72	72



Report Runtime: 2022-02-15 3:11 PM Health Product: See Search Criteria

Total Number of Reports: 87 All Age: ΑII

Health Product Role:

Gender:

All Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

			21	100 St. 100 St.	
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Alcohol test positive	2	2	2	2
	Amphetamines positive	1	1	1	1
	Analgesic drug level above therapeutic	1 1	10 1 14-20-/	1	1
	Antidepressant drug level above therapeutic	3	3	3	3
	Benzodiazepine drug level therapeutic	1 1	1 1 1.4-1./	1	1
	Blood ethanol increased	1	1	1	1
Investigations	Electrocardiogram QT prolonged	3	3	3	3
-	Opiates positive	5	5	5	5
	Postmortem blood drug level	2	2	2	2
	Postmortem blood drug level abnormal	2	2	2	2
	Postmortem blood drug level increased	3	3	3	3
	Serum serotonin increased	1	1	1	1
	Toxicologic test abnormal	3	3	3	3
	X-ray	1	1	1	1
	SOC Subtotal	29	29	29	29

A2021001919



Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

All

Total Number of Reports: 87 Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		2021		4410	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Metabolism and	Decreased appetite	2	2	2	2
nutrition disorders	Metabolic acidosis	1	1	1	1
	SOC Subtotal	3	3	3	3
Musculoskeletal	Back pain	1		1	1
and connective tissue disorders	Pain in extremity	1	1	1	1
	SOC Subtotal	2	2	2	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hepatic cancer	2	2	2	2
200	SOC Subtotal	2	2	2	2
	Brain injury	1	1	1	1
	Brain oedema	2	2	2	2
Nervous system disorders	Burning sensation	1	1	1	1
	Coma	1	1 1	1	1
	Depressed level of consciousness	1	1	1	1
	Dizziness	7	7	7	7

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A2021001919



Report Runtime: 2022-02-15 3:11 PM Health Product: See Search Criteria

All

Total Number of Reports: All Age: All

Health Product Role:

Gender:

Seriousness:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

87

		2021		5010	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Haemorrhage intracranial	1	1	1	1
	Headache	1 1	1	1	1
	Hypoxic-ischaemic encephalopathy	2	2	2	2
	Ischaemic cerebral infarction	2	22	2	2
	Loss of consciousness	3	3	3	3
Nervous system disorders	Mental impairment	2	. 2	2	2
	Serotonin syndrome	2	2	2	2
	Somnolence	4	4	4	4
	Speech disorder	1	1	1	1
	Status epilepticus	2	2 1024	2	2
	Unresponsive to stimuli	7	7	7	7
	SOC Subtotal	40	40	40	40
Pregnancy, puerperium and perinatal conditions	Foetal death	2	2	2	2
	SOC Subtotal	2	2	2	2



Report Runtime: 2022-02-15 3:11 PM Health Product: See Search Criteria

Total Number of Reports: 87 All Age: All

Health Product Role:

Gender:

All Seriousness:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

			21		
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Anxiety	1	1	1	1
	Completed suicide	5	5	5	5
	Confusional state	4	4	4	4
	Depression	16	16	16	16
Psychiatric	Drug abuse	13	13	13	13
	Drug dependence	3,	3	3	3
disorders	Insomnia	1	1	1	1
	Mental disorder	2	2	2	2
	Psychiatric decompensation	1	1	1	1
	Sleep disorder	1.1	3: 1	1	1
	Suicidal ideation	1	1	1	1
	Suicide attempt	45 1	1	1	1
	SOC Subtotal	49	49	49	49
Reproductive system and breast disorders	Benign prostatic hyperplasia	2	2	2	2
	SOC Subtotal	2	2	2	2

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A2021001919



Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

All

Age: All Gender: All

Health Product Role:

MedDRA Version:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

- - - -

Total Number of Reports:

Foreign or Domestic: Domestic

87

		2021		6.05	
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Asphyxia	2	2	2	2
	Asthma	2	2	2	2
	Нурохіа			1	1
	Oropharyngeal pain	1	1	1	1
Respiratory, thoracic and mediastinal disorders	Pneumonitis	2	2	2	2
	Pulmonary congestion	2	2	2	2
	Pulmonary embolism	2	2	2	2
	Respiratory depression	2	2	2	2
	Wheezing	1		1	1

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A2021001919



Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria

All

Total Number of Reports: 87
Age: All
Gender: All

Health Product Role:

Initial Date of Receipt:

MedDRA Version:

Seriousness:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	21	F101	
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	SOC Subtotal	15	15	15	15
Skin and subcutaneous tissue disorders	Angioedema	1	1	1	1
	SOC Subtotal	1	1	1	1
Social circumstances	Loss of personal independence in daily activities	4	4	4	4
	SOC Subtotal	4	4	4	4
Surgical and	Laparotomy	1	1	1	1
medical procedures	Therapy change	2	2	2	2
	SOC Subtotal	3	3	3	3
	Deep vein thrombosis	1	1	1	1
Vascular disorders	Hypotension	2	2	2	2
vascular disorders	Pallor	1	1	1	1
	Shock		11	1	1
	SOC Subtotal	5	5	5	5
Broad Deep Control	Grand Total	325	325	325	325



Search Criteria

Report Runtime:	2022-02-15 - 2:27 PM 1.07 minutes
Range for Initial Date Received	2021-01-01 to 2021-12-31
AER No(s)	
Country of Occurence	Domestic
Case Serious?	All
Case Outcome	Fatal
Report Source	All
Patient Gender	All
Range for Age (years)	All
Reporter Type	All
Source Company Unit	All
Product Role	
Product Class	All
Product Description	All
DIN/NPN	
	amitriptylin hydrochloride amitriptyline pamoate AMITRIPTYLINE EMBONATE Amitriptyline AMITRIPTYLINOXIDE AMITRIPTYLINE HCL AMITRIPTYLINE? PERPHENAZINE AMITRIPTYLINE AMITRIPTYLINE AMITRIPTYLINE AMITRIPTYLINE AMITRIPTYLIN Amitriptyline Pamoate Amitriptyline hydrochloride Amitriptylinoxide amitriptylinoxide Amitriptyline Hydrochloride Amitriptyline Hydrochloride Amitriptyline Hydrochloride AMITRIPTYLINE CHLORIDE

CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement. (10/2007).



Glossary/Abbreviations

7	Гегт	Definition	
	Age	Age of the patient when the adverse reaction reports and age specific searches with all how the company of the adverse reaction reports and age specific searches with the company of the patient when the adverse reaction reports and age specific searches with the company of the patient when the adverse reaction reports and age specific searches with the company of the patient when the adverse reaction reports and age specific searches with the company of the patient when the adverse reaction reports and age specific searches with the company of the patient when the adverse reaction reports and age specific searches with the company of the company of the patient when the adverse reaction reports and age specific searches with the company of the co	
	AR	Adverse Reaction AMITRIPTYLINE HYDROCHLORIDE? PERPHENAZIN aripiprazole lauroxil	
Ger	nder	Gender of the patient as it was provided by the reaction reports and gender specific selipines will not include reports where the gender is unknown aripiprazole (anhydrous)	lverse 1.
Health Pr o	duct	A health product includes drugs and natural pestizonoducts. Drugs include both prescription and represcription pharmaceuticals; biotechnology products and biologically-derived products such as vaccines, serums, and blood derived products and radiopharmaceuticals.	non-
Health Pro	duct Role	The characterization of the role of the Andril Class Politically Resignal reporter of the adverse reaction. The health product role reporter suspected the health product relationships play a reporter suspected the health product was not suspected by the reporter of the adverse reaction.	the that
	HLT	High Level Term – see definition of MARTINE	
н	LGT	Asenapine Maleate High Level Group Term – see definitions of high Le	
Initial Da	te of ceipt	The date that the first version of the adverse reaction report was received by Health Canada's Canasenapine maleate quetiapine	ada
Med	DRA	Medical Dictionary for Regulatory Activities HARMER ISMARKETIZE tionally recognized standardize of terms used to facilitate the regulation of the breading Medical Meddrage Meddrage Meddrage groups relate adverse reacterms in a hierarchical structure whereby the breading (PT) is grouped under the broader he of 'high level term' (HLT). 'High level terms' are then grouped under 'high level group terms (HLGT) which are then grouped by 'system organ class' (SOC). The 'preferred term' is the most specific terms are then grouped adverse Reactions' while the system organ class' is the most general. Quetiapina	tion ading)
MedDRA Ver	sion	The MedDRA terminology is updated இரு நால் pushes scheduled basis. The MedDRA version displated reflects the version in use at the time விருந்திருள்ளுள்ளது.	iyed
	NEC	Not Elsewhere Classified – MedDRA abbreviation Cariprazine hydrochloride	
1	NOS	Not Otherwise Specified – MedDRA abareprizatione Hydrochloride	
	PT	Cariprazine Preferred Term – A MedDRA Preferred Term is an adverse reaction term which is a distinct description (single medical concept) for a symptom, sign, disease, diagnosis, therapeutic indication, investigation of medical procedure, and medical, social, or family history characteristic. cariprazine	otor on,
Seriousi	ness	The seriousness of the adverse reaction representation of the seriousness of the adverse reaction of the required in-patient hospitalization of the representation of the results in persistent of the results in the re	genital
•	soc	System Organ Class – A System Organ Class is a System Organ Class of System Organ Class – A System Organ Class is a System Organ Class of System Organ Cla	2
		CHLORPROMAZINE HYDROCHLORIDE Chlorpromazine Hydrochloride CHLORPROMAZINE HIBENZATE CHLORPROMAZINE PHENOLPHTHALINATE	

	shlarnramazina ambanata
	chlorpromazine embonate
	Chlorpromazine Embonate
	CHLORPROMAZINE TANNATE
	chlorpromazine hydrochloride
	CHLORPROMAZINE PROMETHAZINE COMBINED D
	CHLORPROMAZINE_PROMETHAZINE COMBINED [
	zuclopenthixol acetate
	ZUCLOPENTHIXOL DIHYDROCHLORIDE
	Zuclopenthixol Acetate
	ZUCLOPENTHIXOL
	zuclopenthixol PECANOATE
	ZUCLOPENTHIXOL DECANOATE
	zuclopenthixol hydrochloride
	ZUCLOPENTHIXOL ACETATE
	Zuclopenthixol Hydrochloride
	Zuclopenthixol
	zuclopenthixol decanoate
	zuclopenthixol dihydrochloride
	ZUCLOPENTHIXOL HYDROCHLORIDE
	Zuclopenthixol Decanoate
	clozapine
	Clozapine CLOZAPINE
	FLUPENTIXOL DIHYDROCHLORIDE
	Flupentixel
	flupentixel
	flupentixol
	Flupentixol Dihydrochloride Flupentixol Decanoate
	flupentixol dihydrochloride
	flupentixol hydrochloride
	FLUPENTIXOL
	FLUPENTIXOL DECANOATE
	FLUPENTIXOL? MELITRACEN
	SULPIRIDE ADAMANTANECARBOXYLATE
	Levosulpiride
	levosulpiride
	SULPIRIDE
	DIAZEPAM? SULPIRIDE
	sulpiride
	LEVOSULPIRIDE
	Sulpiride
	amisulpiride
	Fluphenazine Decanoate
	fluphenazine enanthate
	fluphenazine hydrochloride
	fluphenazine maleate
Active Ingredient(s)	1 *
Active Ingredient(s)	Fluphenazine Hydrochloride fluphenazine enantate fluphenazine

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	FLUPHENAZINE DECANOATE
	fluphenazine decanoate
	FLUPHENAZINE HYDROCHLORIDE
	Fluphenazine
	FLUPHENAZINE
	haloperidol
	Haloperidol Decanoate
	Haloperidol
	HALOPERIDOL LACTATE
	haloperidol decanoate
	haloperidol 2mg/ml
	HALOPERIDOL
	HALOPERIDOL DECANOATE
	haloperidol lactate
	HALOPERIDOL? ILOPERIDONE
	Paliperidone
	Paliperidone Palmitate
	paliperidone
	PALIPERIDONE
	lurasidone
	Lurasidone
	Lurasidone Hydrochloride
	lurasidone hydrochloride
	LURASIDONE
	LURASIDONE HYDROCHLORIDE
	Lurasidone hydrochloride
	LEVOMEPROMAZINE
	Levomepromazine Maleate
	LEVOMEPROMAZINE EMBONATE
	Levomepromazine Embonate
220 (1997) - 1997 (1997) - 1997 (1997) - 1997 (1997) - 1997 (1997) - 1997 (1997) - 1997 (1997) - 1997 (1997) -	LEVOMEPROMAZINE HYDROCHLORIDE
	levomepromazine embonate
	levomepromazine hydrochloride
	LEVOMEPROMAZINE MALEATE
	Levomepromazine Hydrochloride
	levomepromazine maleate
	levomepromazine
	Levomepromazine
	methotrimeprazine
	methotrimeprazine hydrochloride
	Periciazine
	PERICIAZINE NECULATE
	PERICIAZINE MESILATE
	periciazine
	PROPERICIAZINE
	study-drug-olanzapine
	Olanzapine Pamoate

OLANZAPINE HYDROCHLORIDE
olanzapine
OLANZAPINE EMBONATE
Olanzapine
OLANZAPINE? ZIPRASIDONE
olanzapine embonate
OLANZAPINE
Olanzapine Embonate
pimozide
Pimozide
PIMOZIDE
prochlorperazine
Prochly opposition
PROCHLORPERAZINE
prochlorperazine mesilate
Prochlorperazine Edisylate
prochlorperazine mesylate
Prochlorperazine PROCHLORPERAZINE MESILATE
prochlorperazine hydrochloride prochlorperazine maleate
PROCHLORPERAZINE EDISYLATE
PROCHLORPERAZINE MALEATE
prochlorperazine edisylate
PROMAZINE HYDROCHLORIDE
TRIFLUPROMAZINE
promazine
triflupromazine
PROMAZINE
ACEPROMAZINE MALEATE
Promazine Hydrochloride
ACEPROMAZINE
triflupromazine hydrochloride
Promazine
promazine hydrochloride
acepromazine
acepromazine maleate
RISPERIDONE
(RISPERIDONE
risperidone
RISPERIDONE NON-COMPANY IMP
Risperidone
amisulpride
AMISULPRIDE
Amisulpride
TRIFLUOPERAZINE
Trifluoperazine Hydrochloride
TRANYLCYPROMINE SULFATE? TRIFLUOPERAZIN
TRIFLUOPERAZINE/TRIFLUOPERAZINE HYDROCHI
TRIFLUOPERAZINE HYDROCHLORIDE

	trifluoperazine trifluoperazine hydrochloride DESVENLAFAXINE SUCCINATE MONOHYDRATE desvenlafaxine Desvenlafaxine Desvenlafaxine succinate desvenlafaxine succinate desvenlafaxine succinate monohydrate DESVENLAFAXINE Desvenlafaxine Succinate desvenlafaxine Succinate desvenlafaxine Succinate DESVENLAFAXINE SUCCINATE
Dosage Form	All
Route of Administration	All
ATC	All
ATC Pattern	All
Reaction PTs	All

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-15 2:27 PMTotal Number of Reports:670Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

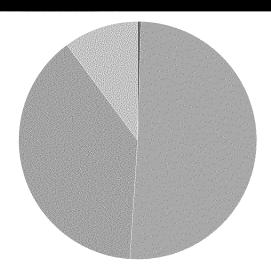
Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousr	ness	
			Death	668	
	1,449 670			Life Threatening	13
1,449 670		670 670	Hospitalization required	53	
			Disability	5	
			Congenital Anomaly	1	
			Other Medically	266	

Age Group					
ADOLES CENT	3	0.45%			
ADULT	339	50.60%			
ELDERLY	260	38.81%			
UNKNOW N	68	10.15%			

	Patient Sex	
Female	256	38.21%
Male	408	60.90%
Not specified	5	0.75%
Unknown	1	0.15%



MedDRA Version:



■ ADOLESC... ■ ADULT ■ ELDERLY...

The Definition for age groups has been taken from the International Conference on Harmonization (ICH) and have been defined as follows:

- Neonate greater than zero and up to 27 days, inclusively
- Infant greater than 27 days and less than 2 years
- Child greater or equal to 2 and less than 12 years
- Adolescent greater or equal to 12 and less than 19 years
- Adult greater or equal to 19 and less than 65 years
- Elderly greater or equal to 65 years

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

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Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

System Organ Class	Number of All Reactions*	Reactions* (% of total)	Number of Reactions* where outcome of AR report was fatal
Blood and lymphatic system disorders	25	1.73%	8
Cardiac disorders	135	9.32%	29
Endocrine disorders	1	0.07%	1
Eye disorders	2	0.14%	2
Gastrointestinal disorders	31	2.14%	18
General disorders and administration site conditions	583	40.23%	39
Hepatobiliary disorders	12	0.83%	6
Infections and infestations	69	4.76%	15
Injury, poisoning and procedural complications	124	8.56%	29
Investigations	59	4.07%	26
Metabolism and nutrition disorders	21	1.45%	11
Musculoskeletal and connective tissue disorders	13	0.90%	9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	39	2.69%	16
Nervous system disorders	116	8.01%	43
Pregnancy, puerperium and perinatal conditions	2	0.14%	1
Psychiatric disorders	84	5.80%	23
Renal and urinary disorders	9	0.62%	5
Respiratory, thoracic and mediastinal disorders	85	5.87%	29
Skin and subcutaneous tissue disorders	3	0.21%	3
Social circumstances	4	0.28%	1
Surgical and medical procedures	16	1.10%	7
Vascular disorders	16	1.10%	9
Total Number of Reactions	1,449	100.00%	330

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

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MedDRA Version: Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

System Organ Class			Number of
		Number of All Reactions*	Reactions* where outcome
HLT	[PT	reactions	of report was fatal
Blood and lymphatic system disorde	rs		
Anaemias nonhaemolytic and marrow depre	ession		
Marrow depression and hypoplastic anaemias	Pancytopenia	1	1
Spleen, lymphatic and reticuloendothelial s	ystem disorders		
Lymphatic system disorders NEC	Lymphadenopathy	3	3
	-		
White blood cell disorders			
Loukoputagoa NEC	Leukocytosis	5	5
Leukocytoses NEC	Neutrophilia	4	4
Leukopenias NEC	Leukopenia	3	3
	Agranulocytosis	1	1
Neutropenias	Granulocytopenia	7	7
	Neutropenia	1	1
Blood and lym	phatic system disorders SOC Total	25	25
]	
Cardiac disorders			
Cardiac arrhythmias			
Cardiac conduction disorders	Bundle branch block right	1	1
	Arrhythmia	11	11
Rate and rhythm disorders NEC	Bradycardia	5	5

Supraventricular arrhythmias

Tachycardia

Atrial fibrillation

Sinus bradycardia



3

2

1

3

2

1

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 Health Product: See Search Criteria Αll Age: Health Product Role: Gender: All MedDRA Version:

Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Ventricular arrhythmias and cardiac arrest	Cardiac arrest	25	25
	Cardio-respiratory arrest	5	5
	Pulseless electrical activity	2	2
	Torsade de pointes	12	12
	Ventricular arrhythmia	8	8
	Ventricular fibrillation	9	9

Cardiac disorders, signs and symptoms NEC			
0 11 11 11 11 11 11	Acute cardiac event	1	1
Cardiac disorders NEC	Cardiac disorder	4	4

Cardiac valve disorders			
Mitral valvular disorders	Mitral valve incompetence	1	1

Coronary artery disorders			
Cananam Lantam disandana NEC	Arteriosclerosis coronary artery	1	1
Coronary artery disorders NEC	Coronary artery disease	1	1
Ischaemic coronary artery disorders	Acute coronary syndrome	2	2
	Myocardial infarction	10	10
	Myocardial ischaemia	1	1
	Myocardial reperfusion injury	8	8

Heart failures			
	Cardiac failure	10	10
Heart failures NEC	Cardiac failure chronic	1	1
	Cardiac failure congestive	1	1

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



Report Runtime:

Canada

2022-02-15 2:27 PM

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670

Canada Vigilance Summary of Product Adverse Reactions

Total Number of Reports:

Health Product: See Search Criteria Age: Αll Health Product Role: All Gender: MedDRA Version: Seriousness: Foreign or Domestic: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Domestic Myocardial disorders 1 1 Cardiomegaly 2 2 Myocardial disorders NEC Left ventricular dysfunction 1 1 Myocardial hypoxia 4 Noninfectious myocarditis Myocarditis 4 Pericardial disorders 2 2 Pericardial disorders NEC Pericardial effusion **Cardiac disorders SOC Total** 135 135 **Endocrine disorders** Thyroid gland disorders Thyroid hypofunction disorders 1 1 Hypothyroidism **Endocrine disorders SOC Total** 1 1 Eye disorders Eye disorders NEC 1 1 Lacrimation disorders Lacrimation increased Ocular neuromuscular disorders 1 Pupil disorders 1 Pupil fixed Eye disorders SOC Total 2 2 Gastrointestinal disorders Abdominal hernias and other abdominal wall conditions Umbilical hernias 3 3 Umbilical hernia

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



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Domestic

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 Health Product: See Search Criteria Αll Age: Health Product Role: Gender: All

MedDRA Version: Seriousness: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic:

Gastrointestinal motility and defaecation con-	ditions		
	Constipation	1	1
Gastrointestinal atonic and hypomotility disorders NEC	Intestinal dilatation	1	1
	Intestinal pseudo-obstruction	1	1

Gastrointestinal signs and symptoms			
Faecal abnormalities NEC	Faecaloma	2	2
Gastrointestinal signs and symptoms NEC	Anal incontinence	1	1
	Odynophagia	3	3
Nausea and vomiting symptoms	Discoloured vomit	2	2
	Nausea	4	4
	Vomiting	1	1

Gastrointestinal stenosis and obstruction			
Duodenal and small intestinal stenosis and obstruction	Small intestinal obstruction	2	2
Gastrointestinal stenosis and obstruction NEC	Ileus	1	1
	Intestinal obstruction	2	2
	Malignant gastrointestinal obstruction	1	1

Gastrointestinal ulceration and perforation			
Intestinal ulcers and perforation NEC	Large intestine perforation	1	1

Gastrointestinal vascular conditions			
Gastrointestinal vascular occlusion and infarction	Intestinal ischaemia	1	1

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

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Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Peritoneal and retroperitoneal conditions			
Peritoneal and retroperitoneal disorders	Ascites	3	3
1 Chicked and recoperitorious alcordere	Ascites		

Salivary gland conditions			
Oral dryness and saliva altered	Salivary hypersecretion	1	1

Gastrointestinal disorders SOC Total	31	31
--------------------------------------	----	----

General disorders and administration site conditions

Body temperature conditions			
Body temperature altered	Hyperthermia	1	1
	Hypothermia	1	1
	Temperature regulation disorder	2	2
Febrile disorders	Pyrexia	7	7

Fatal outcomes			
Death and sudden death	Accidental death	9	9
	Brain death	9	9
	Death	455	455
	Drowning	1	1
	Hanging	1	1
	Sudden cardiac death	1	1
	Sudden death	1	1

General system disorders NEC			
Asthenic conditions	Asthenia	4	4
	Fatigue	5	5
	Malaise	10	10
Feelings and sensations NEC	Temperature intolerance	1	1

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-15 2:27 PMTotal Number of Reports:670Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Gait disturbances	Gait inability	1	1
	Condition aggravated	2	2
	General physical health deterioration	8	8
	III-defined disorder	1	1
	Illness	2	2
General signs and symptoms NEC	Multiple organ dysfunction syndrome	3	3
	Organ failure	1	1
	Swelling	2	2
	Terminal state	1	1
	Unmasking of previously unidentified disease	2	2
Mucosal findings abnormal	Mucosal dryness	1	1
Oedema NEC	Face oedema	2	2
	Oedema	1	1
	Oedema peripheral	5	5
D	Chest pain	2	2
Pain and discomfort NEC	Pain	1	1

Therapeutic and nontherapeutic effects (e	excl toxicity)		
Interactions	Drug interaction	21	21
	Food interaction	2	2
	Potentiating drug interaction	2	2
	Tobacco interaction	1	1
Therapeutic and nontherapeutic responses	Drug ineffective	2	2
	Paradoxical drug reaction	4	4
	Therapeutic product effect incomplete	3	3

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MedDRA Version: Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

|--|

	General disorders and administration site conditions SOC Total	583	583
--	----------------------------------------------------------------	-----	-----

Hepatobiliary disorders

Hepatic and hepatobiliary disorders			
Hepatic failure and associated disorders	Hepatic failure	3	3
Hepatic fibrosis and cirrhosis	Hepatic cirrhosis	2	2
Hepatic vascular disorders	Congestive hepatopathy	2	2
Hepatocellular damage and hepatitis NEC	Hepatic steatosis	1	1
	Hepatitis	2	2
	Liver injury	2	2

Hepatobiliary disorders SOC Total	12	12

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MedDRA Version:

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Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

nfections and infestations			
Bacterial infectious disorders			
Bacterial infections NEC	Stenotrophomonas infection	1	1
Staphylococcal infections	Staphylococcal infection	1	1
Infections - pathogen unspecified			
Cardiac infections	Endocarditis	1	1
Infections NEC	Infection	3	3
	Pneumonia	22	22
Lower respiratory tract and lung infections	Pneumonia aspiration	10	10
	Pneumonia necrotising	1	1
	Bacteraemia	1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis	2	2

Viral infectious disorders			
	Coronavirus infection	2	2
Coronavirus infections	COVID-19	14	14
	COVID-19 pneumonia	7	7
	Suspected COVID-19	1	1

Urosepsis

Kidney infection

Infections and infestations SOC Total	69	69

Exposures, chemical injuries and poisoning

Urinary tract infections

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2

1

2

1

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:

2022-02-15 2:27 PM

Total Number of Reports:

670

Αll

All

Health Product: Health Product Role:

Initial Date of Receipt:

See Search Criteria

Gender: MedDRA Version:

Age:

Seriousness:

Al

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	1	1
Non-occupational environmental exposures	Exposure to extreme temperature	3	3
Poisoning and toxicity	Toxicity to various agents	17	17

Injuries by physical agents			
Heat injuries (excl thermal burns)	Heat stroke	3	3
Thermal burns	Thermal burn	1	1

Injuries NEC			
Cerebral injuries NEC	Brain herniation	3	3
New site and sife in invite NEO	Fall	7	7
Non-site specific injuries NEC	Road traffic accident	1	1
Site specific injuries NEC	Head injury	4	3
Skin injuries NEC	Contusion	3	3

ledication errors and other product use error	s and issues		
Medication errors, product use errors and	Product use in unapproved indication	2	2
issues NEC	Product use issue	1	1
	Accidental overdose	2	2
	Contraindicated product administered	2	2
Product administration errors and issues	Inappropriate schedule of product administration	4	4
	Incorrect route of product administration	1	1
	Product dose omission issue	4	4
	Wrong patient received product	1	1
Product dispensing errors and issues	Product dispensing error	1	1

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

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Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Product monitoring errors and issues	Labelled drug-drug interaction issue	3	3
, and the second	Product monitoring error	1	1
Product transcribing errors and communication issues	Product communication issue	1	1

Off label uses and intentional product misuses/use issues			
Intentional product use issues	Intentional product use issue	2	2
Off label uses	Off label use	22	22

Overdoses and underdoses NEC			
	Intentional overdose	2	2
Overdoses NEC	Overdose	21	20
	Prescribed overdose	5	5
Underdoses NEC	Underdose	2	2

Procedural related injuries and complications NE	С		
Non-site specific procedural complications	latrogenic injury	4	4

Injury, poisoning and procedural complications SOC Total	124	122
----------------------------------------------------------	-----	-----

Investigations

Cardiac and vascular investigations (excl enzy	me tests)		
ECG investigations	Electrocardiogram QT prolonged	12	12
Heart rate and pulse investigations	Heart rate decreased	1	1
Vascular tests NEC (incl blood pressure)	Blood pressure decreased	2	2

Enzyme investigations NEC			
Skeletal and cardiac muscle analyses	Troponin increased	3	3

Haematology investigations (incl blood groups)

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2022-02-15 2:27 PM Total Number of Reports: 670 Report Runtime: Health Product: See Search Criteria Age: ΑII All Health Product Role: Gender: MedDRA Version: Seriousness: All Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic 1 1 Neutrophil count increased White blood cell analyses 1 1 White blood cell count increased Investigations, imaging and histopathology procedures NEC 1 1 Imaging procedures NEC X-ray Metabolic, nutritional and blood gas investigations 3 Blood gas and acid base analyses Oxygen saturation decreased 3 Neurological, special senses and psychiatric investigations 1 Neurologic diagnostic procedures 1 Coma scale abnormal Physical examination and organ system status topics Physical examination procedures and 1 1 organ system status Body temperature abnormal Protein and chemistry analyses NEC Chemistry analyses NEC 1 1 Serum serotonin increased Renal and urinary tract investigations and urinalyses 1 1 Renal function analyses Blood creatinine increased Toxicology and therapeutic drug monitoring Analgesic drug level above 1 1 therapeutic Antidepressant drug level above 3 3 therapeutic Therapeutic drug monitoring analyses Antipsychotic drug level 4 4 decreased Benzodiazepine drug level 1 1 therapeutic Toxicology laboratory analyses 2 2 Alcohol test positive

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

	Amphetamines positive	2	2
	Blood ethanol	1	1
	Blood ethanol increased	1	1
Toxicology laboratory analyses	Opiates positive	5	5
	Postmortem blood drug level	4	4
	Postmortem blood drug level increased	2	2
	Toxicologic test abnormal	3	3

Water, electrolyte and mineral investigations			
Month	Blood phosphorus decreased	1	1
Mineral and electrolyte analyses	Blood sodium decreased	1	1

		1
Investigations SOC Total	59	59

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

2022-02-15 2:27 PM Report Runtime: Total Number of Reports: 670 Health Product: See Search Criteria Αll Age: Health Product Role All Gender:

Seriousness:	All	Gend	er: •RA Version:	All	
Initial Date of Receipt:	2021-01-01 to 2021-12-31		gn or Domestic:	Domestic	;
Metabolism and ทเ					
Appetite and general	I nutritional disorders				
Appetite disorders		Decreased appetite	3		3
Appente disorders	,	Food refusal	1		1
		Failure to thrive	1		1
General nutritiona	l disorders NEC	Malnutrition	1		1
		Starvation	1		1
Electrolyte and fluid	balance conditions				
Potassium imbala	200	Hyperkalaemia	1		1
r otassium imbala	nce	Hypokalaemia	5		5
0 5 1 1		Hypernatraemia	1		1
Sodium imbalance		Hyponatraemia	3		3
Total fluid volume	decreased	Dehydration	3		3
		1			
Glucose metabolism	disorders (incl diabetes me	litus)			

Glucose metabolism disorders (incl diabetes mellitus)			
Hyperglycaemic conditions NEC	Hyperglycaemia	1	1

Metabolism and nutrition disorders SOC To	otal 21	21

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 Health Product: See Search Criteria Αll Age: Haratte Dandonsk Dal

Health Product Role: Seriousness:	All	Gender: MedDRA Versio	All		
itial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domes					
Musculoskeletal ar	nd connective tissue o	disorders			
Muscle disorders			_		
Muscle pains		Myalgia	3	3	
Muscle related sig	ns and symptoms NEC	Muscle spasms	2	2	
Muscle tone abnor	em alitina	Muscle rigidity	1	1	
iviuscie tone apnoi	mailues	Trismus	1	1	
Musculoskeletal and	connective tissue disorder	s NEC			
	nd connective tissue	Mobility decreased	1	1	
conditions NEC		Musculoskeletal stiffness	2	2	
Musculoskeletal a infections and infla	nd connective tissue ammations NEC	Fasciitis	1	1	
Musculoskeletal and connective tissue		Back pain	1	1	
pain and discomfo	rt	Pain in extremity	1	1	
Muscu	loskeletal and connec	ctive tissue disorders SOC Total	13	13	
maoa	ioonorotal and oomio		10		
Neoplasms benign	, malignant and unsp	ecified (incl cysts and polyps)			
Gastrointestinal neo	olasms malignant and unsp	pecified			
Colorectal neoplas	sms malignant	Colorectal cancer metastatic	1	1	
Pancreatic neoplasms malignant (exclislet cell and carcinoid)		Pancreatic carcinoma	2	2	
Leukaemias					
Leukaemias NEC		Leukaemia	1	1	
				-	
Lymphomas NEC					

Lymphoma

Lymphomas unspecified NEC



1

1

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Health

Canada

Canada Vigilance Summary of Product Adverse Reactions

2022-02-15 2:27 PM Total Number of Reports: 670 Report Runtime: Health Product: See Search Criteria Age: ΑII Health Product Role: Αll Gender: MedDRA Version: Seriousness: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Lymphomas non-Hodgkin's B-cell 1 B-cell lymphomas NEC 1 B-cell lymphoma 1 1 Mantle cell lymphomas Mantle cell lymphoma Metastases 1 1 Metastases to specified sites Metastases to liver Miscellaneous and site unspecified neoplasms malignant and unspecified 2 2 Metastatic neoplasm Neoplasms malignant site unspecified NEC 13 13 Neoplasm malignant Nervous system neoplasms malignant and unspecified NEC Central nervous system neoplasms 1 1 malignant NEC Brain cancer metastatic 1 1 Glial tumours malignant Glioblastoma Nervous system neoplasms unspecified 1 1 malignancy NEC Brain neoplasm Respiratory and mediastinal neoplasms malignant and unspecified Non-small cell neoplasms malignant of the respiratory tract cell type specified 1 1 Lung adenocarcinoma 1 1 Lung cancer metastatic Respiratory tract and pleural neoplasms malignant cell type unspecified NEC 10 10 Lung neoplasm malignant 1 1 Respiratory tract small cell carcinomas Small cell lung cancer metastatic ms benign, malignant and unspecified (incl cysts and polyps) SOC Total 39 39 Nervous system disorders Central nervous system vascular disorders Central nervous system haemorrhages 1 1 and cerebrovascular accidents Cerebellar infarction

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 Health Product: See Search Criteria Αll Age: Health Product Role: Αll Gender:

ModDDA Va

Seriousness: All		MedDRA Version:		
nitial Date of Receipt: 2021	-01-01 to 2021-12-31	Foreign or Domes	stic: Dome	estic
		Cerebral haemorrhage	1	1
		Cerebrovascular accident	4	4
Central nervous system ha and cerebrovascular accide	emorrhages ents	Haemorrhage intracranial	1	1
		Ischaemic cerebral infarction	2	2
		Ischaemic stroke	1	1
Central nervous system vascular disorders NEC		Cerebral amyloid angiopathy	2	2
Encephalopathies				
		Encephalopathy	3	3
Encephalopathies NEC		Hypoxic-ischaemic encephalopathy	13	13
Encephalopathies toxic and	l metabolic	Hepatic encephalopathy	2	2
Headaches				
Headaches NEC		Headache	1	1
Increased intracranial pressu	re and hydrocephali	us		
Increased intracranial pres	sure disorders	Brain oedema	2	2

Increased intracranial pressure and hydrocephal			
Increased intracranial pressure disorders	Brain oedema	2	2
<u> </u>			

Mental impairment disorders			
Alzheimer's disease (incl subtypes)	Dementia Alzheimer's type	2	2
Dementia (excl Alzheimer's type)	Dementia	5	5
	Frontotemporal dementia	1	1
	Vascular dementia	1	1
Mental impairment (excl dementia and memory loss)	Mental impairment	2	2

Movement disorders (incl parkinsonism)

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-15 2:27 PMTotal Number of Reports:670Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: A

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Dyskinesias and movement disorders	Dyskinesia	2	2
NEC	Tardive dyskinesia	2	2
Paralysis and paresis (excl cranial nerve)	Paralysis	1	1
Parkinson's disease and parkinsonism	Parkinsonism	3	3
	Parkinson's disease	4	4
Tremor (excl congenital)	Tremor	4	4

MedDRA Version:

Neurological disorders NEC			
Coma states	Coma	1	1
	Apallic syndrome	1	4
	Depressed level of consciousness	3	3
Disturbances in consciousness NEC	Lethargy	2	2
	Loss of consciousness	5	5
	Somnolence	9	9
Nervous system disorders NEC	Neurotoxicity	3	3
	Clonus	1	1
Newslands of the second and the NEO	Dizziness	1	1
Neurological signs and symptoms NEC	Myoclonus	3	3
	Unresponsive to stimuli	1	1
Sensory abnormalities NEC	Neuralgia	3	3
Speech and language abnormalities	Speech disorder	3	3

Neuromuscular disorders			
	Hypotonia	1	1
Muscle tone abnormal	Neuroleptic malignant syndrome	2	2
	Serotonin syndrome	2	2

Seizures (incl subtypes)

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Canada Vigilance Summary of Product Adverse Reactions Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 Health Product: See Search Criteria Age: ΑII Health Product Role: All Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic 1 1 Epilepsy Seizures and seizure disorders NEC 5 5 Seizure 2 2 Status epilepticus Structural brain disorders 7 7 Structural brain disorders NEC Brain injury **Nervous system disorders SOC Total** 116 116 Pregnancy, puerperium and perinatal conditions Abortions and stillbirth Stillbirth and foetal death 2 2 Foetal death Pregnancy, puerperium and perinatal conditions SOC Total 2 **Psychiatric disorders** Anxiety disorders and symptoms 8 8 Agitation Anxiety symptoms 4 4 Anxiety Changes in physical activity 1 Stereotypies and automatisms Posturing 1 Deliria (incl confusion) 12 12 Confusion and disorientation Confusional state 1 1 Deliria Delirium Depressed mood disorders and disturbances

Depressive disorders	Depression	16	16	į
	•	•	*	



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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 Health Product: See Search Criteria Age: ΑII Health Product Role: All Gender: MedDRA Version: Seriousness: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Mood alterations with depressive 1 1 symptoms Depressed mood Disturbances in thinking and perception 1 Delusional symptoms 1 Delusion of reference Hallucination 5 5 Hallucinations (excl sleep-related) 1 1 Hallucination, auditory Personality disorders and disturbances in behaviour 2 Behaviour and socialisation disturbances 2 Aggression Psychiatric and behavioural symptoms NEC 1 1 Abnormal behaviour NEC Abnormal behaviour Psychiatric symptoms NEC 2 2 Psychiatric decompensation Psychiatric disorders NEC 2 2 Mental disorders NEC Mental disorder 4 4 Drug abuse Substance related and addictive disorders 1 1 Drug dependence Schizophrenia and other psychotic disorders Psychotic disorder NEC 5 5 Psychotic disorder 2 2 Schizophrenia NEC Schizophrenia Sleep disorders and disturbances Disturbances in initiating and maintaining 1 1 sleep Insomnia 1 1 Sleep disorders NEC Sleep disorder

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and consumer).

Suicidal and self-injurious behaviours NEC



Bladder and urethral symptoms

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3

3

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 See Search Criteria Αll Health Product: Age: Health Product Role: All Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic 1 1 Assisted suicide Suicidal and self-injurious behaviour 11 11 Completed suicide 1 1 Suicidal ideation

Psychiatric disorders SOC Total	84	84	
---------------------------------	----	----	--

Renal and urinary disorders			
Renal disorders (excl nephropathies)			
Renal disorders NEC	Renal disorder	3	3
Renal failure and impairment	Renal failure	1	1
Renal vascular and ischaemic conditions	Renal tubular necrosis	1	1
Renai vasculai anu ischaemic conultions	Renai tubular necrosis		
Urinary tract signs and symptoms			

Renal and urinary disorders SOC Total	0	0

Urinary incontinence

Urinary retention

Respiratory, thoracic and mediastin			
Bronchial disorders (excl neoplasms)			
Bronchospasm and obstruction	Chronic obstructive pulmonary disease	2	2
,	Wheezing	4	4

wer respiratory tract disorders (excl obstru	ction and infection)		
Lower respiratory tract inflammatory and immunologic conditions	Pneumonitis	2	2
	Acute pulmonary oedema	5	5
Pulmonary oedemas	Acute respiratory distress syndrome	1	1
	Pulmonary congestion	2	2

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MedDRA Version:

1

1

Santé Canada

Pulmonary oedemas

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-15 2:27 PMTotal Number of Reports:670Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Pleural disorders			
Pneumothorax and pleural effusions NEC	Pleural effusion	2	2

Pulmonary oedema

Pulmonary vascular disorders			
Pulmonary thrombotic and embolic conditions	Pulmonary embolism	12	12

espiratory disorders NEC			
	Dyspnoea	7	7
	Dyspnoea exertional	3	3
	Dyspnoea paroxysmal nocturnal	3	3
	Hypoventilation	1	1
Breathing abnormalities	Orthopnoea	3	3
	Respiratory arrest	1	1
	Respiratory depression	2	2
	Respiratory distress	1	1
	Sleep apnoea syndrome	1	1
Conditions associated with abnormal gas	Asphyxia	3	3
exchange	Нурохіа	4	4
0	Productive cough	3	3
Coughing and associated symptoms	Sputum discoloured	3	3
Description (failures (such a sector)	Acute respiratory failure	1	1
Respiratory failures (excl neonatal)	Respiratory failure	5	5
Description to a total discourt of NEC	Aspiration	2	2
espiratory tract disorders NEC	Respiratory disorder	1	1

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670

Health Product: See Search Criteria Age: All

Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Respiratory tract signs and symptoms			
	Choking	6	6
Upper respiratory tract signs and symptoms	Oropharyngeal pain	1	1
	Rhinorrhoea	3	3

Respiratory, thoracic and mediastinal disorders SOC Total	85	85
-----------------------------------------------------------	----	----

Skin and subcutaneous tissue disorde	ers		
Cutaneous neoplasms benign			
Skin cysts and polyps	Dermal cyst	1	1
Epidermal and dermal conditions			
Dermal and epidermal conditions NEC	Skin disorder	1	1
Skin appendage conditions			
Apocrine and eccrine gland disorders	Hyperhidrosis	1	1
Skin and subcuta	neous tissue disorders SOC Total	3	3
Social circumstances			
Lifestyle issues			
Disability issues	Loss of personal independence in daily activities	4	4
	Social circumstances SOC Total	4	4

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Psychiatric therapies

2022-02-15 2:27 PM

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3

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Total Number of Reports:

Health Product: See Search Criteria Αll Age: Health Product Role: Gender: All Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Surgical and medical procedures Gastrointestinal therapeutic procedures 1 1 Abdominal therapeutic procedures NEC Laparotomy Psychiatric therapeutic procedures

Therapeutic procedures and supportive of	care NEC		
	Drug therapy enhancement	3	3
	Hospitalisation	4	4
Therapeutic procedures NEC	Multiple drug therapy	3	3
	Surgery	1	1
	Therapy change	1	1

Anxiolytic therapy

Surgical and medical procedures SOC Total	16	16

2022-02-15 2:27 PM

Report Runtime:

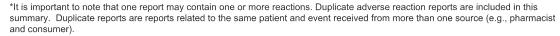
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Canada Vigilance Summary of Product Adverse Reactions

Total Number of Reports:

Health Product: See Search Criteria Age: Αll Health Product Role: All Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Vascular disorders Aneurysms and artery dissections Aneurysms and dissections non-site 1 specific Aneurysm 1 Arteriosclerosis, stenosis, vascular insufficiency and necrosis Non-site specific necrosis and vascular 2 2 insufficiency NEC Arteriosclerosis Decreased and nonspecific blood pressure disorders and shock 1 1 Circulatory collapse and shock Circulatory collapse 2 2 Vascular hypotensive disorders Hypotension **Embolism and thrombosis** Peripheral embolism and thrombosis 4 4 Deep vein thrombosis Vascular disorders NEC Non-site specific vascular disorders NEC 1 1 Vasodilatation 1 1 Site specific vascular disorders NEC Pallor Vascular haemorrhagic disorders 1 1 Haemorrhages NEC Internal haemorrhage Vascular hypertensive disorders 3 3 Vascular hypertensive disorders NEC Hypertension Vascular disorders SOC Total 16 16







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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports:
Health Product: See Search Criteria Age:
Health Product Role: Gender:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

			250 (1757)						2021							
		Jan	uary	Febr	uary	Ma	March		April		May		ne	Ju	ily	August
soc	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Agranulocytosis						1									
	Granulocytopenia			2	2			2	2	16	1					
	Leukocytosis							110						3	3	
Blood and lymphatic	Leukopenia					2	2									
system disorders	Lymphadenopathy							1	<u> </u>							2
	Neutropenia					1	1									
	Neutrophilia	27						1	2-1/2					2	2	
	Pancytopenia							1	1							
	SOC Subtotal			2	2	4	4	6	6	1	1			5	5	2
	Acute cardiac event													1,	1	
	Acute coronary syndrome	1	1													
Cardiac disorders	Arrhythmia			1	1:1:							1	::::-1 ;:::::	1		1
	Arteriosclerosis coronary artery	1	4													
	Atrial fibrillation					1	1		ستان در استان در	 سندم می استار کار						
	Bradycardia			1	1					1	1					

670

All

ΑII



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports:
Health Product: See Search Criteria Age:
Health Product Role: Gender:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

				100		20)21	100 000 000 000 20 00 000				
			Septe	ember	Oct	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Agranulocytosis										1	1
	Granulocytopenia						1	1	4	1	7	7
	Leukocytosis								1.7		5	5
Blood and lymphatic	Leukopenia						1	1			3	3
system disorders	Lymphadenopathy	2									3	3
	Neutropenia										1	1
	Neutrophilia								1	1	4	4
	Pancytopenia										1	1
es estable adapte displace allocations	SOC Subtotal	2					2	2	3	3	25	25
	Acute cardiac event										1	1
	Acute coronary syndrome		1	1							2	2
Cardina dinandana	Arrhythmia	1:1:					1	1	::::::7.::::::	7	11	11
Cardiac disorders	Arteriosclerosis coronary artery										1	1
	Atrial fibrillation					درون دومن روزور کی			11	[::::1;:::::	2	2
	Bradycardia		1	1			2	2			5	5

670 All

All



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

							1000		2021							
		Jan	uary	Febr	uary	Ma	rch	April		May		June		Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Bundle branch block right					1	1									
	Cardiac arrest			3	3	6	6			1	1	1	1	1	1	
	Cardiac disorder	4:	2,	J==1:	1		J	71	11		Ż,	2		2,1,	2:1:	
	Cardiac failure			1	1	·		f-1				1	1	2	2	1
	Cardiac failure chronic	1	1			2;		2,				2		Z;		2
	Cardiac failure congestive									1	1					
	Cardiomegaly	[177														
	Cardio-respiratory arrest															
Cardiac disorders	Coronary artery disease			7	2	2 C		2 T						7 Tanana	2	7
	Left ventricular dysfunction															
	Mitral valve incompetence								7			- 	/	7:::1,		
	Myocardial hypoxia															
	Myocardial infarction	[657 1 555	1	: 1	1	1	1,1	1,1,	1			1,1,	1	3,1,	1	
	Myocardial ischaemia															
	Myocardial reperfusion injury															
	Myocarditis			1	1	1	1					1	1	1	1	
	Pericardial effusion	13:		1	11			j			2	1	::1:			J



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

				100.07		20)21	100				
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Bundle branch block right										1	1
	Cardiac arrest				3	3	2	2	8	8	25	25
	Cardiac disorder		2-1-	1:1				2	2	2	4	4
	Cardiac failure	1	1	1					4	4	10	10
	Cardiac failure chronic								2		1	1
	Cardiac failure congestive										1	1
	Cardiomegaly	1777	ر		ر داده در		ر				1	1
	Cardio-respiratory arrest								5	5	5	5
Cardiac disorders	Coronary artery disease		1	1							1	1
	Left ventricular dysfunction				1	1			1	1	2	2
	Mitral valve incompetence						7		7 Tanana		1	1
	Myocardial hypoxia		1	1							1	1
	Myocardial infarction		1	1	1,	1	<u> </u>	<u> </u>	2	2	10	10
	Myocardial ischaemia						1	1			1	1
	Myocardial reperfusion injury							1-	7	7	8	8
	Myocarditis										4	4
	Pericardial effusion	12	5		11.		2	J	2.		2	2



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

			100	56 2000000000000000000000000000000000000				- 25	2021						The same of the sa	
		Jan	uary	Febr	uary	Ma	rch	Ap	oril	May		June		Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Pulseless electrical activity									1	1			1	1	
	Sinus bradycardia															
Cardiac disorders	Tachycardia		4-1	2	2	1	1	The state of the s			1.0000			11.1.		
	Torsade de pointes	11	1													
	Ventricular arrhythmia									1	1			·		2
	Ventricular fibrillation			£ 34.3	- J	1	1		6				£ 5			
	SOC Subtotal	4	4	12	12	11	11	2	2	5	5	6	6	9	9	4
Endocrine disorders	Hypothyroidism	1	1													
	SOC Subtotal	1	1													
									1							
Eye disorders	Lacrimation increased		2 2 ²	1	1	<u> </u>	2					2	2	2		,
	Pupil fixed			1	1											
	SOC Subtotal			2	2											
	Anal incontinence				1											
Gastrointestinal disorders	Ascites							1	1							
	Constipation					1,2	1									
	Discoloured vomit							1	1							



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports:

Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

						20	21					
			Septe	mber	Octo	ober	Nove	mber	Decei	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
STATE OF THE STATE	Pulseless electrical activity										2	2
	Sinus bradycardia						:				1	1
Cardiac disorders	Tachycardia										3	3
	Torsade de pointes						2	2	10	10	12	12
	Ventricular arrhythmia	2							5	5	8	8
	Ventricular fibrillation			<u> </u>	55	55	2	2	6	6	9	9
Service Services	SOC Subtotal	4	8	8	6	6	11	11	57	57	135	135
Endocrine disorders	Hypothyroidism										1	1
	SOC Subtotal										1	1
	Lacrimation increased	1									1	1
Eye disorders	Pupil fixed										1	1
	SOC Subtotal										2	2
	Anal incontinence										1	1
Gastrointestinal	Ascites		1	1					1	1	3	3
disorders	Constipation										1	1
	Discoloured vomit					-			1	1	2	2

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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

							1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		2021	2765 ⁽²⁷						
		Jan	uary	Febr	uary	Ma	rch	Ap	ril	Ma	зу	Ju	ne	Ju	ly	August
soc	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Faecaloma									1	1					
	lleus					1	1									
	Intestinal dilatation															
	Intestinal ischaemia															1
	Intestinal obstruction					1	5,19									1
	Intestinal pseudo- obstruction					1	1									
Gastrointestinal	Large intestine perforation					2.127	(-1/2									
disorders	Malignant gastrointestinal obstruction	1	45													
	Nausea				(1	<u> </u>						(1	Q.,1		Ź	
	Odynophagia							1	1							2
	Salivary hypersecretion			<u> </u>	[],.1											
	Small intestinal obstruction							1	1					1	1	
	Umbilical hernia								1							2
	Vomiting															



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

						20	121	F 000 000 000				
			Septe	ember	Oct	ober	Nove	mber	Dece	mber	2000 and 100	
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Faecaloma				1	1					2	2
	lleus										1	1
	Intestinal dilatation										1	1
	Intestinal ischaemia	1									1	1
	Intestinal obstruction										2	2
	Intestinal pseudo- obstruction										1	1
	Large intestine perforation										1	1
Gastrointestinal disorders	Malignant gastrointestinal obstruction										1	1
	Nausea		(J1	Ç1						(J.,1,	4	4
	Odynophagia	2									3	3
	Salivary hypersecretion						<u> </u>				1	1
	Small intestinal obstruction										2	2
	Umbilical hernia	2									3	3
	Vomiting								1	1	1	1



Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

Gender:

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: Health Product: See Search Criteria Age:

Seriousness: All MedDRA Version:

nitial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domesti

Initial Date of Rece	eipt: 2021-01-01 to	2021-12-3	1		Fore	eign or Doi	nestic:	D	omestic							
							1.55		2021							
		Jan	uary	Febr	uary	Ma	rch	Aţ	oril	Mi	зу	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	SOC Subtotal	1	1	3	3	6	6	5	5	1	1	1	1	1	1	6
	Accidental death															2
	Asthenia			1	1	2	2									1
	Brain death															
	Chest pain													1	1	
General disorders and administration site	Condition aggravated															
conditions	Death	48	48	34	34	25	25	37	37	33	33	22	22	60	60	52
	Drowning															
	Drug ineffective															
	Drug interaction			5	5			2	2	Ź	2	4.5	4			2
	Face oedema			1	1							1	1			

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All

ΑII



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Age: All Gender: All

Total Number of Reports:

Health Product Role:

Initial Date of Receipt:

MedDRA Version:

Seriousness:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

						20	121	Fig. 100 - 100 - 100 -				
			Septe	ember	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	SOC Subtotal	6	2	2	1	1			4	4	31	31
	Accidental death	2		57.1				57/ <u>1</u>	4	4	9	9
	Asthenia	1									4	4
	Brain death						2	2	7	7	9	9
	Chest pain		1	1							2	2
General disorders and	Condition aggravated										2	2
administration site conditions	Death	52	28	28	31	31	47	47	38	38	455	455
	Drowning										1	1
	Drug ineffective		1	1					1	1	2	2
	Drug interaction	2	2-	2	11-1				ź	2	21	21
	Face oedema										2	2



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports:

Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

								344	2021							
		Janu	uary	Febr	uary	Ma	rch	Ar	oril	Ma	ıy	Ju	ne	Jı	ıly	August
soc	PT	All Reactions	Outcome Fatal	All Reactions												
State of the State	Fatigue		(1) 1 (1)			1										
	Food interaction															1
	Gait inability									1	1					
	General physical health deterioration	1	1	2	2			1	1			1	1			2
General disorders and administration site	Hanging						1									
conditions	Hyperthermia			1	1											
	Hypothermia															
	III-defined disorder							1	1							
	Illness													1		
	Malaise					2	2	3	3							3

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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports:
Health Product: See Search Criteria Age:

Gender:

Seriousness: All

Health Product Role:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

All

All

				100 cm		20	21	100000000000000000000000000000000000000				
			Septe	mber	Oct	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Fatigue			1			1	1	1	1	5	5
	Food interaction	1							1	1	2	2
	Gait inability										1	1
	General physical health deterioration	2			1	1					8	8
General disorders and administration site	Hanging										1	1
conditions	Hyperthermia										1	1
	Hypothermia										1	1
	III-defined disorder										1	1
	Iliness										2	2
	Malaise	3					1	1	1	1	10	10



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

							100	and the	2021							
		Jan	uary	Febr	uary	Mar	rch	Ар	oril	Mi	ay	Ju	ne	Ju	ily	August
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Mucosal dryness															
	Multiple organ dysfunction syndrome			1	1							1	1			
	Oedema															
	Oedema peripheral			1	1			1	1			1	1			2
General disorders and administration site	Organ failure															
conditions	Pain															
	Paradoxical drug reaction															
	Potentiating drug interaction															1
	Pyrexia		1		1				1							2
	Sudden cardiac death															



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Age: All

Total Number of Reports:

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31 Fore

Foreign or Domestic: Domestic

670

					Hills St. Landson	20	121	000000000000000000000000000000000000000				
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Mucosal dryness						1	1	3,500,000		1	1
	Multiple organ dysfunction syndrome								1	1	3	3
	Oedema							1.1			1	1
	Oedema peripheral	2									5	5
General disorders and	Organ failure										1	1
administration site conditions	Pain		1	1							1	1
	Paradoxical drug reaction	1							3	3	4	4
	Potentiating drug interaction	1							1	14	2	2
	Pyrexìa	2									7	7
	Sudden cardiac death								1	1	1	1



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All

Health Product Role: Gender:
Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

							100		2021							
		Jan	uary	Febr	uary	Ma	rch	Ap	ril	M	ау	Ju	ne	Ju	ily	August
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Sudden death															
	Swelling			1	1							1	1			
	Temperature intolerance															
	Temperature regulation disorder			2	2											
General disorders and administration site conditions	Terminal state															
	Therapeutic product effect incomplete															1
	Tobacco interaction					1										
	Treatment noncompliance			1	1	1	1	1	1			1	1			
	Unmasking of previously unidentified disease															
	SOC Subtotal	51	51	52	52	35	35	47	47	37	37	35	35	64	64	70

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Report Runtime: 2022-02-15 2:27 PM

See Search Criteria Age:

Health Product Role:

Health Product:

Seriousness:

All

Initial Date of Receipt: 2021-01-01 to 2021-12-31

All .

Total Number of Reports: 670

Age: All Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

					The second secon	20	121	200				
			Septe	mber	Oct	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Sudden death		1	1							1	1
	Swelling										2	2
	Temperature intolerance										1	1
	Temperature regulation disorder										2	2
General disorders and administration site conditions	Terminal state										1	1
	Therapeutic product effect incomplete	1							2	2	3	3
	Tobacco interaction										1	1
	Treatment noncompliance								1	1	5	5
	Unmasking of previously unidentified disease				(1)						2	2
	SOC Subtotal	70	37	37	35	35	55	55	65	65	583	583



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 Health Product: All See Search Criteria Age: Gender: ΑII Health Product Role:

All MedDRA Version: Seriousness:

									2021							
		Jan	uary	Febr	uary	Ma	rch	Ar	oril	М	ау	Ju	ine	Ju	ily	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions										
	Congestive hepatopathy			1	1							1	1			
	Hepatic cirrhosis								1	J	2					
Hepatobiliary disorders	Hepatic failure			1	1	1	1					1	1			
	Hepatic steatosis		1													
	Hepatitis			1	1							1	1			
	Liver injury			(11	1			<u> </u>		Z.Z.,		<u> </u>	1.12		Z.,	
	SOC Subtotal			4	4	1	1	1	1			4	4			
															T	
	Bacteraemia					1	1									
	Coronavirus infection		/	1	/ // 1	/	/							7		
	COVID-19	7	7			3	3	1	1					1	1	2
Infections and	COVID-19 pneumonia	3		7	7			1	J	7		7 7			7.53	2
infestations	Endocarditis													1	1	
	Infection					J	1	2 1	1 1	/		J		7 77 8 7 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	- 2 (1)	7
	Kidney infection															
	Pneumonia		77	J	1	3	3	2	22	/1	J1			2	7	4



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

						20	121					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Congestive hepatopathy				3						2	2
	Hepatic cirrhosis									(51)	2	2
Hepatobiliary disorders	Hepatic failure										3	3
	Hepatic steatosis	<u> </u>	2);	35					11	11	1	1
	Hepatitis										2	2
	Liver injury				<u> </u>	£					2	2
	SOC Subtotal								2	2	12	12
	Bacteraemia										1	1
	Coronavirus infection			/	7	/		7 7			2	2
	COVID-19	2									14	14
Infections and	COVID-19 pneumonia	2		/	- 1	7.1	/	7			7	7
infestations	Endocarditis										1	1
	Infection						77				3	3
	Kidney infection		1	1							1	1
	Pneumonia	4			2	2	3	3	6	6	22	22



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 All Health Product: See Search Criteria Age: Gender: ΑII Health Product Role:

All MedDRA Version: Seriousness:

Foreign or Domestic: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Domestic

initial Date of Rec	celpt: 2021-01-01 to					eign or Dor			omestic							
									2021							
		Jani	January		February		March		April		May		June		July	
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
Infections and infestations	Pneumonia aspiration	2	2	1	1	1	1	1	1	2	2	2	2	1	1	200700000000000000000000000000000000000
	Pneumonia necrotising												1/1			
	Sepsis					2	2									
	Staphylococcal infection						1									
	Stenotrophomonas infection					1	1									
	Suspected COVID-19						1/									
	Urosepsis									1	1					1
	SOC Subtotal	13	13	3	3	14	14	6	6	4	4	4	4	3	3	9
Injury, poisoning and procedural complications	Accidental overdose		5									5.5 1				
					1775 2000		<u> </u>		1915 2000		1975,5				1/// /	24 (11)
	Brain herniation							1	1							
	Contraindicated product administered															
	Contusion							1	1							2



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports:

Health Product: See Search Criteria Age: All Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

						20	21					
			Septe	ember	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Pneumonia aspiration										10	10
	Pneumonia necrotising										1	1
	Sepsis										2	2
Infections and infestations	Staphylococcal infection										1	1
	Stenotrophomonas infection										1	1
	Suspected COVID-19	1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -									1	1
	Urosepsis	4									2	2
	SOC Subtotal	9	1	1	3	3	3	3	6	6	69	69
		20001							,			
	Accidental overdose										2	2
Injury, poisoning and	Brain herniation		1	1					1	1	3	3
procedural complications	Contraindicated product administered								2	2	2	2
	Contusion	2									3	3

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Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 Health Product: All See Search Criteria Age: Gender: ΑII

All MedDRA Version: Seriousness:

									2021							
		Jan	uary	Febr	uary	Ma	rch	Ap	ril	Ma	ay	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Exposure during pregnancy															
	Exposure to extreme temperature			1	1									1	1	1
	Fall					2	2									
	Head injury	1														1
Injury, poisoning and procedural	Heat stroke															2
complications	latrogenic injury															1
	Inappropriate schedule of product administration															
	Incorrect route of product administration															
	Intentional overdose												1			
	Intentional product use issue									1	1					



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Total Number of Reports: 670 Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

				- 100 cm		20)21	40.40.40.40.				
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Exposure during pregnancy		1	1							1	1
	Exposure to extreme temperature	1									3	3
	Fall	1		1			2	2) () ()	7	7
	Head injury	1	2	2							4	3
Injury, poisoning and procedural	Heat stroke	2									3	3
complications	latrogenic injury	1							3	3	4	4
	Inappropriate schedule of product administration			1					2	-2	4	4
	Incorrect route of product administration				1	1					1	1
	Intentional overdose										2	2
	Intentional product use issue		1	1							2	2



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports:
Health Product: See Search Criteria Age:

Health Product Role: Gender:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

							1 7 1 7	-24	2021				The state of the s			
		Jan	uary	Febr	uary	Mai	ch	Ар	oril	Ma	ıy	Jui	ne	Ju	ily	August
soc	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions										
	Labelled drug-drug interaction issue															
	Off label use	3	3	1	1	2	2	1	1	2	2	1	1	1	1	1
	Overdose			215	1	4	3					2	2			
	Prescribed overdose									1	1					1
Injury, poisoning and procedural	Product communication issue															
complications	Product dispensing error															1
1	Product dose omission issue															
	Product monitoring error															
	Product use in unapproved indication															
	Product use issue															

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All

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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Total Number of Reports: 670 Age: All

Health Product Role:

Gender:

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

				- 100 cm		20	21	40.40.40.40.				
			Septe	mber	Oct	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Labelled drug-drug interaction issue	1					1	1	1	1	3	3
	Off label use	1	1	1			1	1	8	8	22	22
	Overdose			1	3	3	4	-4	4 7	4	21	20
	Prescribed overdose	1	1	1					2	2	5	5
Injury, poisoning and procedural	Product communication issue			1							1	1
complications	Product dispensing error	1									1	1
	Product dose omission issue								2	2	4	4
	Product monitoring error		1	1							1	1
	Product use in unapproved indication				i	1					2	2
	Product use issue								1	1	1	1



Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 Health Product: All See Search Criteria Age: Gender: ΑII

All MedDRA Version: Seriousness:

Illitial Date of Net	eipi. 2021-01-01 to	2021 12 0	•		1 010	eigh or Doi	nestio.		mesuc							
									2021							
		Jan	uary	Febr	uary	Mai	rch	Ap	ril	Ma	ау	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Road traffic accident	1	1													
	Thermal burn															
njury, poisoning and procedural complications	Toxicity to various agents			2	2	1		2	2			4	4		1	
	Underdose															
	Wrong patient received product															
	SOC Subtotal	7	6	8	8	9	8	5	5	5	5	9	9	3	3	15
	Alcohol test positive			1	1							1	1			
	Amphetamines positive						SA.					10-				
	Analgesic drug level above therapeutic															
nvestigations	Antidepressant drug level above therapeutic												ر روی در			1.7
	Antipsychotic drug level decreased															1
	Benzodiazepine drug level therapeutic	17 mm. 17 mm. 17 mm. 17 mm.										1	1			

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Total Number of Reports: 670
Age: All

Health Product Role:

Gender: All

Seriousness: All

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

						20)21					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Road traffic accident										1	1
	Thermal burn						1	1			1	1
injury, poisoning and procedural complications	Toxicity to various agents				3	3	2	-2	2	2	17	17
	Underdose				1	1			1	1	2	2
	Wrong patient received product										1	1
	SOC Subtotal	15	13	13	9	9	11	11	30	30	124	122
	Alcohol test positive										2	2
	Amphetamines positive					532		532		300	2	2
	Analgesic drug level above therapeutic								1	1	1	1
nvestigations	Antidepressant drug level above therapeutic	1							2	2	3	3
	Antipsychotic drug level decreased	1							3	3	4	4
	Benzodiazepine drug level therapeutic										1	1



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

								2	2021							
		Jan	uary	Febr	uary	Ma	rch	Ap	oril	М	ay	Ju	ne	Ju	ıly	August
soc	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Blood creatinine increased															
	Blood ethanol				(Z.4);	1	[2-1]									
	Blood ethanol increased											1	1			
	Blood phosphorus decreased		5			2 C								7		
	Blood pressure decreased			1	1							1	1			
	Blood sodium decreased			7								7		2		
	Body temperature abnormal															
Investigations	Coma scale abnormal			1	1							2				
	Electrocardiogram QT prolonged															qu.
	Heart rate decreased								درد. د د صول درد در از انجاد		درون درون درون درون درون درون درون درون		والمستوالية			
	Neutrophil count increased													1	1	
	Opiates positive			1	1	1	1	: - /		Z		3	3			
	Oxygen saturation decreased			1	1							1	1			
	Postmortem blood drug level					-1								1		
	Postmortem blood drug level increased											2	2			



Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: Health Product: See Search Criteria Age: Gender:

All MedDRA Version: Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

						20)21	100000000000000000000000000000000000000				
			Septe	mber	Oct	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Blood creatinine increased						1	1			1	1
	Blood ethanol	[1	1
	Blood ethanol increased										1	1
	Blood phosphorus decreased					2	J1		2		1	1
	Blood pressure decreased		·								2	2
	Blood sodium decreased		2		/		J1	2 - 1			1	1
	Body temperature abnormal						1	1			1	1
Investigations	Coma scale abnormal										1	1
	Electrocardiogram QT prolonged	1					2	2	9	9	12	12
	Heart rate decreased		;==1;::::	1				·			1	1
	Neutrophil count increased										1	1
	Opiates positive		7		J.,			7	2		5	5
	Oxygen saturation decreased		1	1							3	3
	Postmortem blood drug level	1								1	4	4
	Postmortem blood drug level increased				(51)						2	2

670 All



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

See Search Criteria Age:
Gender:

Seriousness: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670 All

			45						2021							
		Jani	uary	Febr	uary	Mai	rch	Ap	ril	Ma	зу	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Serum serotonin increased									1	1					
	Toxicologic test abnormal			1	1			1	1			1	1			
Investigations	Troponin increased	1000 mm														2
	White blood cell count increased													1	1	
	X-ray		<i>z</i>	/		1	37:21			/	;		2	2	.e	
	SOC Subtotal			6	6	5	5	2	2	1	1	12	12	3	3	6



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Age: All Gender: All

670

Total Number of Reports:

Health Product Role:

Initial Date of Receipt:

MedDRA Version:

Seriousness: All

2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

					100 pt 10	20	021	2 2 2				
			Septe	mber	Octo	ber	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Serum serotonin increased										1	1
	Toxicologic test abnormal										3	3
Investigations	Troponin increased	2									3	3
	White blood cell count increased										1	1
	X-ray							/			1	1
	SOC Subtotal	6	2	2			6	6	16	16	59	59



Health Product:

Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM

See Search Criteria Age:
Gender:

Seriousness: All

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

All

ΑII

								40	2021				100			
		Jan	uary	Febr	uary	Ma	rch	Ap	oril	M	ay	Ju	ne	Ju	ily	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Decreased appetite	1	1			1	1									
	Dehydration			1	1											1
	Failure to thrive															1
	Food refusal			1	17											
	Hyperglycaemia											1	1			
Metabolism and nutrition disorders	Hyperkalaemia													1		
	Hypernatraemia									1	1					
	Hypokalaemia			227				1	1							2
	Hyponatraemia							1	1							2
	Malnutrition															10
	Starvation															
	SOC Subtotal	2	2	2	2	1	1	2	2	1	1	1	1	1	1	7



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Total Number of Reports: 670
Age: All

Health Product Role:

Gender:

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

						2()21					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Decreased appetite								1	1	3	3
	Dehydration	1,									3	3
	Failure to thrive	1									1	1
	Food refusal										1	1
	Hyperglycaemia										1	1
Metabolism and nutrition disorders	Hyperkalaemia										1	1
	Hypernatraemia										1	1
	Hypokalaemia	2					2	2			5	5
	Hyponatraemia	2									3	3
	Malnutrition	1									1	1
	Starvation				1	1					1	1
	SOC Subtotal	7			1	1	2	2	1	1	21	21



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

2021-01-01 to 2021-12-31

Age: All

Total Number of Reports:

Health Product Role:

Gender: All

670

Seriousness: All

MedDRA Version:

Initial Date of Receipt:

Foreign or Domestic: Domestic

								- 20	2021							
		Jan	uary	Febr	uary	Ma	rch	Ap	oril	М	ay	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions										
	Back pain															
	Fasciitis					1	1									
	Mobility decreased					1										
	Muscle rigidity			1	1											
Musculoskeletal and connective tissue disorders	Muscle spasms															
	Musculoskeletal stiffness			1	1							1	1			
	Myalgia											1				
	Pain in extremity			1	1											
	Trismus													ر المستورية المستورية المستورة المستورة المستورة المستورة المستورة المستورة المستورة المستورة المستورة المستور المستورة المستورة ال		
	SOC Subtotal		1.7.4	6	6	3	3		1		1	3	3	terent medical		



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Report Runtime: 2022-02-15 2:27 PM Health Product: See Search Criteria

All

Total Number of Reports: 670 All Age: All

Health Product Role:

Gender:

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

				300.00		20)21					
			Septe	mber	Oct	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Back pain			1							1	1
	Fasciitis										1	1
	Mobility decreased										1	1
	Muscle rigidity										1	1
Musculoskeletal and connective tissue disorders	Muscle spasms										2	2
	Musculoskeletal stiffness										2	2
	Myalgia										3	3
	Pain in extremity										1	1
	Trismus										1	1
	SOC Subtotal		1	1							13	13



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

			40 30						2021						The second	
		Jani	uary	Febr	uary	Ma	rch	Aŗ	oril	М	ay	Ju	ine	Ju	ıly	August
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	B-cell lymphoma							1	1							
	Brain cancer metastatic															
	Brain neoplasm	1	4				i.									
Neoplasms benign, malignant and unspecified (incl cysts	Colorectal cancer metastatic															
and polyps)	Glioblastoma						:									
	Leukaemia														1	
	Lung adenocarcinoma															
	Lung cancer metastatic)



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

				60 c. 2		20)21	40.40.40.				
			Septe	ember	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	B-cell lymphoma										1	1
	Brain cancer metastatic								1	1	1	1
	Brain neoplasm										1	1
Neoplasms benign, malignant and	Colorectal cancer metastatic								1/-		1	1
unspecified (incl cysts and polyps)	Glioblastoma								1	1	1	1
	Leukaemia										1	1
	Lung adenocarcinoma						1	1			1	1
	Lung cancer metastatic	1									1	1



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Gearch Criteria Age:
Gender:

Seriousness: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

All

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								1	2021							
		Janu	ıary	Febr	ruary	Mai	rch	Ar	oril	М	ay	Ju	ne	Ju	ıly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Lung neoplasm malignant									3	3			2	2	2
	Lymphoma							3.5.1 2.5.1	1							
	Mantle cell lymphoma															1
Neoplasms benign, malignant and unspecified (incl cysts	Metastases to liver															
and polyps)	Metastatic neoplasm	1	1	1	1											
	Neoplasm malignant	1		1	1	2	2	2	2					3. 3.21	1	
	Pancreatic carcinoma															
	Small cell lung cancer metastatic	1														
	SOC Subtotal	4	4	2	2	2	2	4	4	3	3	3.4.71		4	4	4



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Total Number of Reports: 670 Age: All

Health Product Role:

Gender:

Seriousness: All

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

						20)21	10 000 000 000 10 10 10 10 10 10 10 10 10 10 10 10 10 1				
			Septe	mber	Oct	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Lung neoplasm malignant	2					1	1	2	2	10	10
	Lymphoma										1	1
	Mantle cell lymphoma	1									1	1
Neoplasms benign, malignant and	Metastases to liver								1/-		1	1
unspecified (incl cysts and polyps)	Metastatic neoplasm										2	2
	Neoplasm malignant		1	1	- 1	2.4	3	3	35. 35. 1	3 2.1	13	13
	Pancreatic carcinoma						1	1	1	1	2	2
	Small cell lung cancer metastatic										1	1
Talance dispersional street and seek on	SOC Subtotal	4	1	1	1	1	6	6	8	8	39	39



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

				5					2021							
		Jan	uary	Febr	uary	Mai	rch	Ap	oril	M	ау	Ju	ne	Jι	ıly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions								
	Apallic syndrome															
	Brain injury									50	Fy 1					
	Brain oedema							1	1							
	Cerebellar infarction															1
	Cerebral amyloid angiopathy											1	1			
	Cerebral haemorrhage															1
Nervous system	Cerebrovascular accident			1	1	1	1									
disorders	Clonus										ر در					
	Coma															
	Dementia										-1					1
	Dementia Alzheimer's type											1	1			
	Depressed level of consciousness			1	1					1	1,1	1		7/4		
	Dizziness															
	Dyskinesia		775									1	<u></u>			



Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

Gender:

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: Health Product: See Search Criteria Age:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

				318.6.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 14.0.2 1		20)21	2 2 2 2 2 2				
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Apallic syndrome						1	1			1	1
	Brain injury								5	5	7	7
	Brain oedema								1	1	2	2
	Cerebellar infarction	1 1									1	1
	Cerebral amyloid angiopathy				1	1					2	2
	Cerebral haemorrhage	1 07									1	1
Nervous system	Cerebrovascular accident		2	2							4	4
disorders	Clonus				1-						1	1
	Coma		1	1							1	1
	Dementia	217		1,1			1.1	1		54-5	5	5
	Dementia Alzheimer's type				1	1					2	2
	Depressed level of consciousness										3	3
	Dizziness	12.85		1.20.1			1	1		11	1	1
	Dyskinesia				. 1						2	2

670 All



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

									2021							
		Jan	uary	Febr	uary	Mai	rch	Ap	ril	Mi	ау	Ju	ne	Ju	ily	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Encephalopathy			1	1	1	1					1	1			
	Epilepsy															
	Frontotemporal dementia															
	Haemorrhage intracranial								ر استان ا استان استان است							
	Headache															
	Hepatic encephalopathy	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		1	1							1	1			
Nervous system	Hypotonia			1	1											
disorders	Hypoxic-ischaemic encephalopathy															
	Ischaemic cerebral infarction							1	1							
	Ischaemic stroke	1	24				52									
	Lethargy															1
	Loss of consciousness			1	1					(1)	1	1		Eric.		
	Mental impairment															1
	Myoclonus								1.							2



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

				315.127 		20)21					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Encephalopathy										3	3
	Epilepsy						27		-1	1	1	1
	Frontotemporal dementia						1	1			1	1
	Haemorrhage intracranial			1.1							1	1
	Headache		1	1							1	1
	Hepatic encephalopathy	1	373					57			2	2
Nervous system	Hypotonia										1	1
disorders	Hypoxic-ischaemic encephalopathy				1.1.	1	Ż	2	.10	10	13	13
	Ischaemic cerebral infarction								1	1	2	2
	Ischaemic stroke										1	1
	Lethargy	1							1	1	2	2
	Loss of consciousness								1		5	5
	Mental impairment	1	1						1	1	2	2
	Myoclonus	2									3	3



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

									2021							
		Jan	uary	Febr	uary	Ma	rch	Ар	ril	М	ay	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Neuralgia							1	1							2
	Neuroleptic malignant syndrome				1											
	Neurotoxicity		:					1	1							2
	Paralysis	1771	1													
	Parkinsonism					1	1					1	1			
	Parkinson's disease					1	1/			71-	1		1.1			
Nervous system	Seizure	1	1	1	1	1	1					1	1			
disorders	Serotonin syndrome							1	1							
	Somnolence			1	1			1	1					4	1	3
	Speech disorder			2	2							1	5.4.2			
	Status epilepticus															
	Tardive dyskinesia											1.	1			
	Tremor							1	1							2
	Unresponsive to stimuli															



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

					His (1)	20)21	100 000 000 100 000 000				
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
de Daniel de La Companya de La Comp	Neuralgia	2									3	3
	Neuroleptic malignant syndrome				1	(1)	2				2	2
	Neurotoxicity	2									3	3
	Paralysis										1	1
	Parkinsonism				1	1					3	3
	Parkinson's disease								1	1	4	4
Nervous system	Seizure				1	1					5	5
disorders	Serotonin syndrome								1		2	2
	Somnolence	3	1	1			1	1	1	1	9	9
	Speech disorder										3	3
	Status epilepticus				1	1			1	1	2	2
	Tardive dyskinesia		7		1						2	2
	Tremor	2							1	1	4	4
	Unresponsive to stimuli								11		1	1



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Rec	ceipt: 2021-01-01 t	:0 2021-12-3	1		Fore	eign or Doi	mestic:	יט	omestic							
									2021							
		Jan	uary	Febr	uary	Ma	rch	Ap	oril	M	ау	Ju	ne	Jı	uly	August
oc	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions										
ervous system sorders	Vascular dementia	1	1													
	SOC Subtotal	4	4	11	11	5	5	8	8	5	5	12	12	1	1	16
						1										
regnancy, puerperium nd perinatal onditions	Foetal death						577									
	SOC Subtotal															
	Abnormal behaviour			1	1											
	Aggression	2	2													
	Agitation			1	1			1	1			1	1			1
	Anxiety							1	1							2
	Assisted suicide					1	1									
	Completed suicide	1.1	(1)	5.1	(1)	517	(1)	(C1)	(1)	5.1	(1)	2	-2			
	Confusional state			2	2	1	1	1	1			2	2			3
sychiatric disorders	Delirium									1,1	1,1,					
	Delusion of reference															
	Depressed mood				7,50	1										
	Depression			4	4			2	2	1	1	4	4			1
	Drug abuse			1-1-		1	111					1.1.2	1	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	11	
	Drug dependence															
	Hallucination				-			C : 1 :	1	7		(1)	- -1	7.	17,	2



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

						20	21					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber	2000	
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Nervous system disorders	Vascular dementia										1	1
	SOC Subtotal	16	7	7	11	11	8	8	28	28	116	116
Pregnancy, puerperium and perinatal conditions	Foetal death		2	2							2	2
	SOC Subtotal		2	2							2	2
	Abnormal behaviour										1	1
	Aggression			7,5.,		7,7,					2	2
	Agitation	1	1	1					3	3	8	8
	Anxiety	2	1	11				 استسمى دې اختا			4	4
	Assisted suicide										1	1
	Completed suicide		<u> </u>	5.1			- 2	2		67.7	11	11
Psychiatric disorders	Confusional state	3	1	1	1	1			1	1	12	12
esychiatric disorders	Delirium										1	1
	Delusion of reference						1	1			1	1
	Depressed mood		<u> </u>	<u></u>	5.5.7		مارور درور درور درور درور درور درور درور				1	1
	Depression	1	2	2	1	1	1	1			16	16
	Drug abuse										4	4
	Drug dependence								1	1	1	1
	Hallucination	-2	7.	7	£ 21 J	-/1					5	5



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670 Health Product: All See Search Criteria Age: Gender: ΑII Health Product Role:

All MedDRA Version: Seriousness:

				10. 10.					2021							
		Jani	uary	Febr	uary	Ma	arch	Aı		M	ay	Ju	ne	Ji	ıly	August
30C	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Hallucination, auditory				100											
	Insomnia	1	1					J				7	2	2	2	2
	Mental disorder			,		1	1	1	1				<u> </u>			
	Posturing			1,	1	:				Z					7	
Psychiatric disorders	Psychiatric decompensation									1	1			1	1	
	Psychotic disorder	1	531							ر می استان است						5.1
	Schizophrenia			1	1					1	1					
	Sleep disorder												15			
	Suicidal ideation	1	1									·				·
14 Shrara aliagram anapara na linang	SOC Subtotal	6	6	12	12	5	5	8	8	5	5	11	11	2	2	10
				-			-	ļ		ļ						1
	Renal disorder			1	1 1		1					1	1	5.2		
	Renal failure															1
Renal and urinary disorders	Renal tubular necrosis	1;				1	1									
	Urinary incontinence							1	1							2
	Urinary retention							1				30				
1790 200 100 100 100 100 100 100 100 100 100 1	SOC Subtotal			1	1	2	2	2	2			1	1			3



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: Health Product: See Search Criteria Age:

Health Product Role: Gender:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

						20)21					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Hallucination, auditory								1	1	1	1
	Insomnia		2	2	2	2	7	2	2	J	1	1
	Mental disorder										2	2
	Posturing	1		2			Z.:				1	1
Psychiatric disorders	Psychiatric decompensation										2	2
	Psychotic disorder				ر. در دانستان استان		ر. در دانستان المراجعة		3	.3	5	5
	Schizophrenia										2	2
	Sleep disorder	1:		33						1	1	1
	Suicidal ideation										1	1
PARK MARK MARK MARKS	SOC Subtotal	10	7	7	4	4	4	4	10	10	84	84
	Renal disorder										3	3
	Renal failure	1									1	1
Renal and urinary disorders	Renal tubular necrosis										1	1
	Urinary incontinence	2									3	3
	Urinary retention										1	1
600 000 000 000 600 000 000 000	SOC Subtotal	3									9	9

670 All



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

				100 mg/m					2021							
		Jan	uary	Febr	uary	Ma	rch	Ap	ril	Ma	ıy	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Acute pulmonary oedema															1
	Acute respiratory distress syndrome	1														
	Acute respiratory failure	1	1													
	Asphyxia											2	2			
Respiratory, thoracic and mediastinal	Aspiration													1	1	
disorders	Choking				<u> </u>					<u> </u>	5.1		<u></u>	2	2	
	Chronic obstructive pulmonary disease	1	1													
	Dyspnoea							1						1		3
	Dyspnoea exertional							1	1							2
	Dyspnoea paroxysmal nocturnal								<u></u>							2



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports:

Health Product: See Search Criteria Age:
Health Product Role: Gender:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

						20)21	100 100 100				
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Acute pulmonary oedema	1	1	1					3	3	5	5
	Acute respiratory distress syndrome										1	1
	Acute respiratory failure										1	1
	Asphyxia										3	3
Respiratory, thoracic and mediastinal	Aspiration				1	1					2	2
disorders	Choking			1							6	6
	Chronic obstructive pulmonary disease						1	1			2	2
	Dyspnoea	3							1		7	7
	Dyspnoea exertional	2									3	3
	Dyspnoea paroxysmal nocturnal	2									3	3

670 All



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-15 2:27 PM Total Number of Reports: 670
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

							1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		2021							
		Jan	uary	Febr	uary	Ma	rch	Ap	oril	М	ay	Ju	ne	Ju	ly	August
soc	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Hypoventilation															
	Нурохіа					1	1	1	1							2
	Oropharyngeal pain															
	Orthopnoea															2
Respiratory, thoracic and mediastinal	Pleural effusion			1	1							1	1			
disorders	Pneumonitis															
	Productive cough							1	1							2
	Pulmonary congestion															
	Pulmonary embolism					1	1	1	1	2	2					2
	Pulmonary oedema															



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Age: All Gender: All

Health Product Role:

M. IDDAN .

Seriousness: All

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

						20	121					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Hypoventilation		1	1							1	1
	Нурохіа	2									4	4
	Oropharyngeal pain								1	100	1	1
	Orthopnoea	2									3	3
Respiratory, thoracic	Pleural effusion										2	2
and mediastinal disorders	Pneumonitis		3								2	2
	Productive cough	2									3	3
	Pulmonary congestion								1		2	2
	Pulmonary embolism	2					1	1	5	5	12	12
	Pulmonary oedema						} } 				1	1



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Report Runtime: 2022-02-15 2:27 PM Total Number of Reports:
Health Product: See Search Criteria Age:

Health Product Role: Gender:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

				50		207		20	2021							
		Jan	uary	Febr	uary	Mai	rch	Ap	oril	М	ау	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Respiratory arrest															
	Respiratory depression															
	Respiratory disorder				-											
	Respiratory distress															
Respiratory, thoracic and mediastinal disorders	Respiratory failure					1	1	1	1					1	1	2
	Rhinorrhoea								1							2
	Sleep apnoea syndrome															1
	Sputum discoloured		5					1	1							2
	Wheezing					1	1	1	1							2
	SOC Subtotal	3	3	2	2	4	4	11	11	3	3	4	4	5	5	27

670

All

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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Total Number of Reports: 670 Age: All

Health Product Role:

Gender:

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

ΑII

						20)21					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Respiratory arrest								1	1	1	1
	Respiratory depression	T							<u> </u>		2	2
	Respiratory disorder				1	1					1	1
	Respiratory distress		<u></u>								1	1
Respiratory, thoracic and mediastinal disorders	Respiratory failure	2		1							5	5
	Rhinorrhoea	2									3	3
	Sleep apnoea syndrome	1									1	1
	Sputum discoloured	2									3	3
	Wheezing	2									4	4
	SOC Subtotal	27	5	5	3	3	4	4	14	14	85	85



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Age: Gender:

Health Product Role:

Initial Date of Receipt:

MedDRA Version:

Total Number of Reports:

Seriousness: All

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670 All

								- 100	2021							
		Janı	uary	Febi	ruary	Mar	rch	Aŗ	oril	М	ay	Ju	ne	Ju	ly	August
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Dermal cyst													1	1	
Skin and subcutaneous tissue disorders	Hyperhidrosis			1	1											
	Skin disorder															
	SOC Subtotal			1	1									1	1	
Social circumstances	Loss of personal independence in daily activities									1	1					
	SOC Subtotal									1	1					



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Total Number of Reports: 670
Age: All

Health Product Role:

Gender: All

Seriousness: All

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

				3557		20)21					
			Septe	September		ober	Nove	mber	Decei	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Dermal cyst										1	1
Skin and subcutaneous tissue disorders	Hyperhidrosis										1	1
	Skin disorder				1	1					1	1
	SOC Subtotal				1	1					3	3
Social circumstances	Loss of personal independence in daily activities		1	1	1	1	1	1			4	4
	SOC Subtotal		1	1	1	1	1	1			4	4



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

2022-02-15 2:27 PM Total Number of Reports:
See Search Criteria Age:

Health Product Role:

Gender:

Seriousness: All

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670 All

All

		2021														
		Jani	uary	Febr	uary	Ma	rch	Aŗ	oril	M	ay	Ju	ne	Ju	ıly	August
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Anxiolytic therapy															
	Drug therapy enhancement														1	1
	Hospitalisation							1	1					1		
Surgical and medical procedures	Laparotomy					1	1									
	Multiple drug therapy															1
	Surgery					1	1									
	Therapy change	1777								1	-1			\$2000 \$2000		
	SOC Subtotal					2	2	1	1	1	1			1	1	3



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Total Number of Reports: 670 Age: All

Health Product Role:

Gender: All

Seriousness: All

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		2021										
			September		October		November		December			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Anxiolytic therapy	1							2	2	3	3
	Drug therapy enhancement	1							2	2	3	3
	Hospitalisation						2	2			4	4
Surgical and medical procedures	Laparotomy										1	1
	Multiple drug therapy	1							2	2	3	3
	Surgery										1	1
	Therapy change									[2	1	1
e 1900 - Salon Allen Allen o	SOC Subtotal	3					2	2	6	6	16	16



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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

2022-02-15 2:27 PM Total Number of Reports: 670 See Search Criteria Age: All

Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

									2021							
		Jan	uary	Febi	ruary	Ma	rch	Aŗ	oril	Ma	зу	Ju	ne	Ju	uly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Aneurysm															
	Arteriosclerosis	1	1				J	7;	<u> </u>			1	1		2	2
	Circulatory collapse			,		1	1									
	Deep vein thrombosis		Z	2,		Z		J1.	1	1	1			2		2
ascular disorders	Hypertension	1	1													
	Hypotension					3; 1	1	4		2:::1:::::	1					1
	Internal haemorrhage															
	Pallor		Z	2,			1	:						2		
	Vasodilatation			1	1											
	SOC Subtotal	2	2	1	1	3	3	1	1	2	2	1	1			2
										1		T	1			
	Grand Total	98	97	130	130	112	111	111	111	75	75	104	104	103	103	184



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Report Runtime: 2022-02-15 2:27 PM

2022-02-15 2:27 PM Total Number of Reports: 670 See Search Criteria Age: All

Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

			2021									
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Aneurysm				1	1					1	1
	Arteriosclerosis	13	2,	2	2	2	7	2	2	7	2	2
	Circulatory collapse		f-1i			-1			Admini-		1	1
	Deep vein thrombosis	2	Z				2		Z		4	4
Vascular disorders	Hypertension						1	1	1	1	3	3
	Hypotension		2			J.;		J.,			2	2
	Internal haemorrhage								1	1	1	1
	Pallor	I	7								1	1
	Vasodilatation										1	1
	SOC Subtotal	2			1	1	1	1	2	2	16	16
		100/2001						1				
	Grand Total	184	87	87	77	77	116	116	252	252	1,449	1,447



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Total Number of Reports: 670
Age: All
Gender: All

Health Product Role: Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Agranulocytosis	1	1	1	1
	Granulocytopenia	7	7	7	7
Blood and lymphatic system	Leukocytosis	5	5	5	5
	Leukopenia	3	3	3	3
disorders	Lymphadenopathy	3	3	3	3
	Neutropenia	1	1	1	1
	Neutrophilia	4	4	4	4
	Pancytopenia	1	1	1	1
	SOC Subtotal	25	25	25	25
	Acute cardiac event	<u></u>	11	1	1
Cardiac disorders	Acute coronary syndrome	2	2	2	2
Tarango disorders	Arrhythmia	(11 Tag	11	11	11
	Arteriosclerosis coronary artery	1	1	1	1



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

See Search Criteria Age:
Gender:

Seriousness: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670 All

All

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Atrial fibrillation	2	2	2	2
	Bradycardia	5	5	5	5
	Bundle branch block right			1	1
	Cardiac arrest	25	25	25	25
	Cardiac disorder	4	4	4	4
	Cardíac failure	10	10	10	10
	Cardiac failure chronic	3 1	1	1	1
	Cardiac failure congestive	1	1	1	1
	Cardiomegaly			1	1
Cardiac disorders	Cardio-respiratory arrest	5	5	5	5
	Coronary artery disease			1	1
	Left ventricular dysfunction	2	2	2	2
	Mitral valve incompetence			1	1
	Myocardial hypoxia	1	1	1	1
	Myocardial infarction	10	10	10	10
	Myocardial ischaemia	1	1	1	1
	Myocardial reperfusion injury	8	8	8	8
	Myocarditis	4	4	4	4



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Age: All Gender: All

670

Health Product Role:

MedDRA Version:

Total Number of Reports:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

illitial Date of	•	P		· Constitution Statement	
		20	21		
soc	PT.	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Pericardial effusion	2	2	2	2
	Pulseless electrical activity	2	2	2	2
	Sinus bradycardia		1	1	1
Cardiac disorders	Tachycardia	3	3	3	3
	Torsade de pointes	12	12	12	12
	Ventricular arrhythmia	8	8	8	8
	Ventricular fibrillation	9	9	9	9
1960 SEE 1960 SEE	SOC Subtotal	135	135	135	135
Endocrine disorders	Hypothyroidism	1	1	1	1
	SOC Subtotal	1	1	1	1
Eye disorders	Lacrimation increased	11	[1	1	1
Zyo aloo. ao, o	Pupil fixed	1	1	1	1
	SOC Subtotal	2	2	2	2
	Anal incontinence	1		1	1
	Ascites	3	3	3	3
Gastrointestinal disorders	Constipation	12 1	1	1	1
	Discoloured vomit	2	2	2	2
	Faecaloma	2	2	2	2



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Health Product: See Search Criteria

All

Age: All Gender: All

Total Number of Reports:

Health Product Role:

MedDRA Version:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	lleus	1	1	1	1
	Intestinal dilatation	1	1	1	1
	Intestinal ischaemia	1	1	1	1
	Intestinal obstruction	2	2	2	2
	Intestinal pseudo- obstruction	1	1	1	1
	Large intestine perforation	1		1	1
Gastrointestinal disorders	Malignant gastrointestinal obstruction	1	1	1	1
	Nausea	4	4	4	4
	Odynophagia	3	3	3	3
	Salivary hypersecretion	:: 1	1	1	1
	Small intestinal obstruction	2	2	2	2
	Umbilical hernia	3	3	3	3
	Vomiting	1	1	1	4
	SOC Subtotal	31	31	31	31



Report Runtime: 2022-02-15 2:27 PM Health Product: See Search Criteria

All Age: ΑII

Health Product Role:

Gender:

Total Number of Reports:

All Seriousness:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

670

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Accidental death	9	9	9	9
	Asthenia	4	4	4	4
	Brain death	9	9	9	9
	Chest pain	2	2	2	2
	Condition aggravated	2	2	2	2
General disorders and administration site conditions	Death	455	455	455	455
	Drowning	1	1	1	1
	Drug ineffective	2	2	2	2
	Drug interaction	21	21	21	21
	Face oedema	2	2	2	2
	Fatigue	5	5	5	5



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Total Number of Reports: 670 Age: All

Health Product Role:

Gender: All

Seriousness: All

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	21		
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Food interaction	2	2	2	2
	Gait inability	1	1	1	1
	General physical health deterioration	8	8	8	8
	Hanging	1	1	1	1
	Hyperthermia	1	1	1	1
General disorders and administration site conditions	Hypothermia	1		1	1
	III-defined disorder	1	1	1	1
	Illness	2	2	2	2
	Malaise	10	10	10	10
	Mucosal dryness	1	1	1	1
	Multiple organ dysfunction syndrome	3	3	3	3



Report Runtime: 2022-02-15 2:27 PM Health Product: See Search Criteria

All

Total Number of Reports: 670 All Age: All

Health Product Role:

Gender:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

MedDRA Version:

Foreign or Domestic: Domestic

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Oedema	1	1	1	1
	Oedema peripheral	5	5	5	5
	Organ failure	1		1	1
	Pain	1	1	1	1
	Paradoxical drug reaction		4	4	4
General disorders and administration site conditions	Potentiating drug interaction	2	2	2	2
	Pyrexia	7	7	7	7
	Sudden cardiac death	1	1	1	1
	Sudden death		1	1	1
	Swelling	2	2	2	2
	Temperature intolerance	1		1	1

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Health Product: See Search Criteria

All

Total Number of Reports: 670 Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

	PT	2021			
soc		All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Temperature regulation disorder	2	2	2	2
	Terminal state	1	1	1	1
General disorders	Therapeutic product effect incomplete	3	3	3	3
and administration site conditions	Tobacco interaction	1 1	1 1	1	1
	Treatment noncompliance	5	5	5	5
	Unmasking of previously unidentified disease	2	.2	2	2
(1911) (1911) (1911) (1911)	SOC Subtotal	583	583	583	583



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Age: All Gender: All

Total Number of Reports:

Health Product Role:

MedDRA Version:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Congestive hepatopathy	2	2	2	2
	Hepatic cirrhosis	2	2 2	2	2
Hepatobiliary	Hepatic failure	3	3	3	3
disorders	Hepatic steatosis	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1	1	1
	Hepatitis	2	2	2	2
	Liver injury	2	2	2	2
	SOC Subtotal	12	12	12	12
	Bacteraemia	1	1	1	1
	Coronavirus infection	2	2	2	2
	COVID-19	14	14	14	14
Infections and	COVID-19 pneumonia	7	7	7	7
infestations	Endocarditis	1	1	1	1
	Infection	3	3	3	3
	Kidney infection	1	1	1	1
	Pneumonia	22	22	22	22

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Report Runtime: 2022-02-15 2:27 PM Health Product: See Search Criteria

2021-01-01 to 2021-12-31

Health Product Role:

Initial Date of Receipt:

Seriousness:

All

Total Number of Reports: 670

All Age: ΑII

Gender:

MedDRA Version:

Foreign or Domestic: Domestic

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Pneumonia aspiration	10	10	10	10
	Pneumonia necrotising	1	1.	1	1
	Sepsis	2	2	2	2
Infections and infestations	Staphylococcal infection	1	1	1	1
	Stenotrophomonas infection	1	1	1	1
	Suspected COVID-19	5 1	F-1 HOLA	1	1
	Urosepsis	2	2	2	2
	SOC Subtotal	69	69	69	69
	Accidental overdose	2	2	2	2
	Brain herniation	3	3	3	3
Injury, poisoning and procedural complications	Contraindicated product administered	2	2	2	2
	Contusion	3	3	3	3
	Exposure during pregnancy	1	1	1	1

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Health Product: See Search Criteria

See Search Criteria Age: All Gender: All

Seriousness: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

		20	21	100 pt	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Exposure to extreme temperature	3	3	3	3
	Fall	7	7	7	7
	Head injury	4	3	4	3
	Heat stroke	3	3	3	3
	latrogenic injury	4	4	4	4
Injury, poisoning and procedural complications	Inappropriate schedule of product administration	4	-4	4	4
	Incorrect route of product administration	1	1	1	1
	Intentional overdose	2	2	2	2
	Intentional product use issue	2	2	2	2
	Labelled drug-drug interaction issue	3	::	3	3
	Off label use	22	22	22	22



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Health Product: See Search Criteria

All

Total Number of Reports: 670 Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	21	Total All Reactions	
SOC	PT	All Reactions	Outcome Fatal		Total Outcome Fatal
	Overdose	21	20	21	20
	Prescribed overdose	5	5	5	5
	Product communication issue	1	1	1	1
	Product dispensing error	1	1	1	1
	Product dose omission issue	4	4	4	4
Injury, poisoning and procedural complications	Product monitoring error	1	1	1	1
	Product use in unapproved indication	2	2	2	2
	Product use issue	1	1	1	1
	Road traffic accident	1	1	1	1
	Thermal burn	1	1	1	1
	Toxicity to various agents	17.	17	17	17



Report Runtime: 2022-02-15 2:27 PM Total Nu Health Product: See Search Criteria Age:

Health Product Role:

Seriousness:

All

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 670

Age: All Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

		20	21	957	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Injury, poisoning and procedural	Underdose	2	2	2	2
complications	Wrong patient received product	7 1	1	1	1
e della distanti di	SOC Subtotal	124	122	124	122
	Alcohol test positive	2	2	2	2
	Amphetamines positive	2	2	2	2
	Analgesic drug level above therapeutic	1	1	1	1
	Antidepressant drug level above therapeutic	3	3	3	3
	Antipsychotic drug level decreased	4	4	4	4
Iat-ati-	Benzodiazepine drug level therapeutic	12-14-	1	1	1
Investigations	Blood creatinine increased	1	1	1	1
	Blood ethanol	1 ;;	1	1	1
	Blood ethanol increased	1	1	1	1
	Blood phosphorus decreased	1: 1	5 1 9	1	1
	Blood pressure decreased	2	2	2	2
	Blood sodium decreased	1 1		1	1

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Report Runtime: 2022-02-15 2:27 PM Health Product: See Search Criteria

Total Number of Reports: 670 All Age: ΑII

Health Product Role:

Gender:

All Seriousness:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

	PT	20	21		
SOC		All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Body temperature abnormal	1	1	1	1
	Coma scale abnormal	1	2-15	1	1
	Electrocardiogram QT prolonged	12	12	12	12
	Heart rate decreased	S	11	1	1
	Neutrophil count increased	1	1	1	1
	Opiates positive	5	5	5	5
	Oxygen saturation decreased	3	3	3	3
Investigations	Postmortem blood drug level	4	4	4	4
	Postmortem blood drug level increased	2	2	2	2
	Serum serotonin increased		1 1 1 1 1	1	1
	Toxicologic test abnormal	3	3	3	3
	Troponin increased	3	3	3	3
	White blood cell count increased	1	1	1	1
	X-ray	1	1	1	1
	SOC Subtotal	59	59	59	59



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Health Product: See Search Criteria

ia Age: All Gender: All

Seriousness: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

	PT	20	21	Total All Reactions	
soc		All Reactions	Outcome Fatal		Total Outcome Fatal
	Decreased appetite	3	3	3	3
	Dehydration	3	3	3	3
	Failure to thrive	1	1	1	1
	Food refusal	7 1	- 1	1	1
	Hyperglycaemia	1	1	1	1
Metabolism and nutrition disorders	Hyperkalaemia	1	1	1	1
	Hypernatraemia	1	1	1	1
	Hypokalaemia	5	5	5	5
	Hyponatraemia	3	3	3	3
	Malnutrition	1	- 1 - 1/2	1	1
	Starvation	1	1	1	1
	SOC Subtotal	21	21	21	21



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Age: All Gender: All

Health Product Role:

MedDRA Version:

Seriousness:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

		20	21	Total All Reactions	
soc	PT	All Reactions	Outcome Fatal		Total Outcome Fatal
	Back pain	1	1	1	1
	Fasciitis	1	1	1	1
	Mobility decreased			1	1
	Muscle rigidity	1	1	1	1
Musculoskeletal and connective tissue disorders	Muscle spasms	2	2	2	2
	Musculoskeletal stiffness	2	2	2	2
	Myalgia	3	3	3	3
	Pain in extremity	1	1	1	1
	Trismus	1		1	1
	SOC Subtotal	13	13	13	13
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	B-cell lymphoma	1	1	1	1



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Health Product: See Search Criteria

Age: All Gender: All

Total Number of Reports:

Health Product Role:
Seriousness: All

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

soc		20	21	Total All Reactions	
	PT	All Reactions	Outcome Fatal		Total Outcome Fatal
	Brain cancer metastatic	1		1	1
	Brain neoplasm	1	1	1	1
	Colorectal cancer metastatic			1	1
	Glioblastoma	1	1	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemia	1	1	1	1
	Lung adenocarcinoma	1	1	1	1
	Lung cancer metastatic	1	1	1	1
	Lung neoplasm malignant	10	10	10	10
	Lymphoma			1	1



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Health Product: See Search Criteria

All

Total Number of Reports: 670 Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

	PT	20	2021		
SOC		All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Mantie cell lymphoma	1	1	1	1
	Metastases to liver	101		1	1
Neoplasms benign, malignant and	Metastatic neoplasm	2	2	2	2
unspecified (incl cysts and polyps)	Neoplasm malignant	13	13	13	13
	Pancreatic carcinoma	2	2	2	2
	Small cell lung cancer metastatic		1	1	1
	SOC Subtotal	39	39	39	39
	Apallic syndrome	1	1	1	1
Nervous system	Brain injury	: 7	7	7	7
disorders	Brain oedema	2	2	2	2
	Cerebellar infarction	1	1 1 1 1 2 2 1 1	1	1



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2021-01-01 to 2021-12-31

Health Product Role:

All

Initial Date of Receipt:

Seriousness:

See Search Criteria

Total Number of Reports: 670 All Age:

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Cerebral amyloid angiopathy	2	2	2	2
	Cerebral haemorrhage	1	1	1	1
	Cerebrovascular accident	4	4	4	4
	Clonus	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1	1	1
	Coma	1	1	1	1
	Dementia	5	5	5	5
	Dementia Alzheimer's type	2	2	2	2
Nervous system disorders	Depressed level of consciousness	3	3	3	3
	Dizziness	1	1	1	1
	Dyskinesia	2	2	2	2
	Encephalopathy	3	3	3	3
	Epilepsy	1,000		1	1
	Frontotemporal dementia	1	1	1	1
	Haemorrhage intracranial	1,-1,-	1	1	1
L	Headache	1	1	1	1

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Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

See Search Criteria Age:
Gender:

Seriousness: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670 All

All

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Hepatic encephalopathy	2	2	2	2
	Hypotonia	1	1	1	1
	Hypoxic-ischaemic encephalopathy	13	13	13	13
	Ischaemic cerebral infarction	2	2	2	2
	Ischaemic stroke	1.5	41/5	1	4
	Lethargy	2	2	2	2
	Loss of consciousness	5	5	5	5
Nervous system disorders	Mental impairment	2	2	2	2
	Myoclonus	3	3	3	3
	Neuralgia	3	3	3	3
	Neuroleptic malignant syndrome	2	2	2	2
	Neurotoxicity	3	3	3	3
	Paralysis	23 1	1 2 2 2	1	1
	Parkinsonism	3	3	3	3
	Parkinson's disease	4	4	4	4



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Health Product: See Search Criteria

See Search Criteria Age: All Gender: All

Seriousness: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

		20	21		
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Seizure	5	5	5	5
	Serotonin syndrome	2	2	2	2
	Somnolence	9	9	9	9
	Speech disorder	3	3	3	3
Nervous system disorders	Status epilepticus	2	2	2	2
	Tardive dyskinesia	2	2	2	2
	Tremor	4	4	4	4
	Unresponsive to stimuli	1 - 1	3-1-1	1	1
	Vascular dementia	1	1	1	1
	SOC Subtotal	116	116	116	116
Pregnancy, puerperium and perinatal conditions	Foetal death	2	2	2	2
7.0	SOC Subtotal	2	2	2	2
Psychiatric disorders	Abnormal behaviour	1	1	1	1
	Aggression	2	2	2	2
	Agitation	8	8	8	8



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Health Product: See Search Criteria

All

Total Number of Reports: 670 Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	21	37.34	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Anxiety	4	4	4	4
	Assisted suicide	1	1	1	1
	Completed suicide	11	11	11	11
	Confusional state	12	12	12	12
	Delirium	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1/3	1	1
Psychiatric disorders	Delusion of reference	1	1	1	1
	Depressed mood	(1	:: 1	1	1
	Depression	16	16	16	16
	Drug abuse	4	4	4	4
	Drug dependence	1	1	1	1
	Hallucination	5	5	5	5
	Hallucination, auditory	1	1	1	1
	Insomnia	(1,	3 1	1	1
	Mental disorder	2	2	2	2
	Posturing	(1)	175	1	1



Report Runtime: 2022-02-15 2:27 PM Health Product: See Search Criteria Age:

Health Product Role:

Seriousness:

All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Total Number of Reports: 670

All Gender: ΑII

MedDRA Version:

Foreign or Domestic: Domestic

		20	21	100 mm m	
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Psychiatric decompensation	2	2	2	2
	Psychotic disorder	5	5	5	5
Psychiatric disorders	Schizophrenia	2	2	2	2
	Sleep disorder	199 1	1	1	1
	Suicidal ideation	1	1	1	1
	SOC Subtotal	84	84	84	84
	Renal disorder	3	3	3	3
	Renal failure	1	1	1	1
Renal and urinary disorders	Renal tubular necrosis	1 1 1 1 1 1 1 1	1 12-1/	1	1
	Urinary incontinence	3	3	3	3
	Urinary retention	1 1		1	1
	SOC Subtotal	9	9	9	9
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	5	5	5	5
	Acute respiratory distress syndrome	7.1		1	1



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Age: All Gender: All

Health Product Role: Seriousness: All

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

		20	21		
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Acute respiratory failure	1	1	1	1
	Asphyxia	3	3	3	3
	Aspiration	2	2	2	2
Respiratory, thoracic and mediastinal disorders	Choking	6	6	6	6
	Chronic obstructive pulmonary disease	2	2	2	2
	Dyspnoea	7	7	7	7
	Dyspnoea exertional	3	3	3	3
	Dyspnoea paroxysmal nocturnal	3	3	3	3
	Hypoventilation	1	1	1	1



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

See Search Criteria Age:
Gender:

Seriousness: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

All

ΑII

		20	21		
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Нурохіа	4	4	4	4
	Oropharyngeal pain	1	1	1	1
Respiratory, thoracic and mediastinal disorders	Orthopnoea	3	3	3	3
	Pleural effusion	2	2	2	2
	Pneumonitis	2	2	2	2
	Productive cough	3	3	3	3
	Pulmonary congestion	2	2	2	2
	Pulmonary embolism	12	12	12	12
	Pulmonary oedema	1	1	1	1



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

Age: All Gender: All

Health Product Role:

Initial Date of Receipt:

MedDRA Version:

Total Number of Reports:

Seriousness:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

670

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Respiratory arrest	1	1	1	1
	Respiratory depression	2	2	2	2
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	1	1	1	1
	Respiratory distress			1	1
	Respiratory failure	5	5	5	5
	Rhinorrhoea	3	3	3	3
	Sleep apnoea syndrome	1	1	1	1
	Sputum discoloured	3	3	3	3
	Wheezing	4	4	4	4



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

All

2021-01-01 to 2021-12-31

Age: All Gender: All

Total Number of Reports:

Health Product Role:

Initial Date of Receipt:

MedDRA Version:

Seriousness:

Foreign or Domestic: Domestic

670

		20	21	107	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
100 m 245 100 m	SOC Subtotal	85	85	85	85
	Dermal cyst	1	1 1	1	1
Skin and subcutaneous tissue disorders	Hyperhidrosis	1	1	1	1
	Skin disorder	1	1	1	1
fina final light that	SOC Subtotal	3	3	3	3
Social circumstances	Loss of personal independence in daily activities	4	4	4	4
	SOC Subtotal	4	4	4	4
	Anxiolytic therapy	3	3	3	3
	Drug therapy enhancement	3	3	3	3
	Hospitalisation	4	4 (1/10/10/10	4	4
Surgical and medical procedures	Laparotomy	1	1	1	1
	Multiple drug therapy	3	3 3 / 3	3	3
	Surgery	1	1	1	1
	Therapy change	5; 1		1	1
	SOC Subtotal	16	16	16	16



Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria

Total Number of Reports: 670 Age: All

Health Product Role:

Gender: All

Seriousness: All

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Aneurysm	1	1	1	1
	Arteriosclerosis	2	2	2	2
Vascular disorders	Circulatory collapse	1	1	1	1
	Deep vein thrombosis	4	4	4	4
	Hypertension	3	3	3	3
	Hypotension	2	2	2	2
	Internal haemorrhage	1	1	1	1
	Pallor	1	1	1	1
	Vasodilatation	1	1	1	1
	SOC Subtotal	16	16	16	16
	Grand Total	1,449	1,447	1,449	1,447



Search Criteria

Report Runtime:	2022-02-15 - 2:52 PM 2.42 minutes
Range for Initial Date Received	2021-01-01 to 2021-12-31
AER No(s)	
Country of Occurence	Domestic
Case Serious?	All
Case Outcome	Fatal
Report Source	All
Patient Gender	All
Range for Age (years)	All
Reporter Type	All
Source Company Unit	All
Product Role	
Product Class	All
Product Description	All
DIN/NPN	
	amitriptylin hydrochloride amitriptyline pamoate AMITRIPTYLINE EMBONATE Amitriptyline AMITRIPTYLINOXIDE AMITRIPTYLINE HCL AMITRIPTYLINE? PERPHENAZINE AMITRIPTYLINE AMITRIPTYLINE AMITRIPTYLINE AMITRIPTYLINE AMITRIPTYLIN Amitriptyline Pamoate Amitriptyline hydrochloride Amitriptylinoxide amitriptylinoxide Amitriptyline Hydrochloride Amitriptyline Hydrochloride Amitriptyline Hydrochloride AMITRIPTYLINE CHLORIDE

CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement. (10/2007).



Glossary/Abbreviations

Term	Definition	
Age	Age of the patient when the adverse reaction reports and age specific searches with the patient when the adverse reaction reports and age specific searches with the patient when the adverse reaction reports and age specific searches with the patient when the adverse reaction reports and age specific searches with the patient when the adverse reaction reports and age specific searches with the patient when the adverse reaction reports and age specific searches with the patient when the adverse reaction reports and age specific searches with the patient when the adverse reaction reports and age specific searches with the patient when the patient when the adverse reaction reports and age specific searches with the patient with the	е
AR	AMITRIPTYLINE HYDROCHLORIDE? PERPHENAZIN aripiprazole lauroxil	
Gender	Gender of the patient as it was provided by বিশেষটো জিল্ল gender is unknown in some of the adreaction reports and gender specific setil গোলা কৰিছে কৰ	verse 1.
Health Product	A health product includes drugs and natural people (altrivulous) A health product includes drugs and natural people of the products. Drugs include both prescription and represcription pharmaceuticals; biotechnology products and ibiologically-derived products such as vaccines, serums, and blood derived products displacements; and radiopharmaceuticals.	ion-
Health Product Role	The characterization of the role of the ANUREAS A VICE SII ginal reporter of the adverse reaction. The health product role representations in the individual reporter. Cause and effect relations has played been established. A 'suspect' role indicates that reporter suspected the health product capped to adverse reaction. A 'concomitant' role indicates the health product was not suspected by the product taking the health product at the time of the adverse reaction. Asenapine	that
HLT	High Level Term – see definition of MARTHAPINE	
HLGT	Asenapine Maleate High Level Group Term – see definitions of Medical Republic Republ	
Initial Date of Receipt	The date that the first version of the vigilance Program. ASENAPINE MALEATE adverse reaction report was received by Health Canada's Canasenapine maleate quetiapine	ada
MedDRA	Medical Dictionary for Regulatory Activities HAPINEA ISMARATION considered standardized of terms used to facilitate the regulation of terms in a hierarchical structure whereby the breferred term? (PT) is grouped under the broader he of 'high level term' (HLT). 'High level terms' are then grouped under 'high level group terms (HLGT which are then grouped by 'system organ class' (SOC). The 'preferred term' is the most specific terms are then grouped Adverse Reactions! While the System organ class' is the most general. Quetiapina	tion ading `)
MedDRA Version	The MedDRA terminology is updated o្ហោ្រគ្នាប់រាងក្រាង Escheduled basis. The MedDRA version displa reflects the version in use at the time equality in the set of t	iyed
NEC	Not Elsewhere Classified – MedDRA abbreviation Cariprazine hydrochloride	
NOS	Not Otherwise Specified – MedDRA abarepratizione Hydrochloride	
PT	Cariprazine Preferred Term – A MedDRA Preferred Term is a distinct description term which is a distinct description of the process of t	otor on,
Seriousness	The seriousness of the adverse reaction representation of the seriousness of the adverse reaction of the seriousness of the seriousn	genital
soc	System Organ Class – A	}
	CHLORPROMAZINE HIBENZATE CHLORPROMAZINE PHENOLPHTHALINATE	



Company of the compan	hlorpromazine embonate
C	Chlorpromazine Embonate
	CHLORPROMAZINE TANNATE
CI	hlorpromazine hydrochloride
	CHLORPROMAZINE PROMETHAZINE COMBINED D
	CHLORPROMAZINE PROMETHAZINE COMBINED [
	uclopenthixol acetate
	UCLOPENTHIXOL DIHYDROCHLORIDE
	Cuclopenthixol Acetate
	CUCLOPENTHIXOL
	uclopenthixol
	CUCLOPENTHIXOL DECANOATE
	uclopenthixol hydrochloride
	CUCLOPENTHIXOL ACETATE
	Cuclopenthixol Hydrochloride
	· · · · · · · · · · · · · · · · · · ·
	Cuclopenthixol
	uclopenthixol decanoate
	uclopenthixol dihydrochloride UCLOPENTHIXOL HYDROCHLORIDE
	Cuclopenthixol Decanoate
	lozapine
	Clozapine
	CLOZAPINE
	LUPENTIXOL DIHYDROCHLORIDE
	lupentixol
	upentixol decanoate
	upentixol
	lupentixol Dihydrochloride
	lupentixol Decanoate
	upentixol dihydrochloride
	upentixol hydrochloride
	LUPENTIXOL
	LUPENTIXOL DECANOATE
	LUPENTIXOL? MELITRACEN
	SULPIRIDE ADAMANTANECARBOXYLATE
	evosulpiride
	evosulpiride
	SULPIRIDE
	DIAZEPAM? SULPIRIDE
	ulpiride
	EVOSULPIRIDE
S S	Sulpiride
	misulpiride
F	Tuphenazine Decanoate
	uphenazine enanthate
flu	uphenazine hydrochloride
	uphenazine maleate
Active Ingredient(s)	luphenazine Hydrochloride
	uphenazine enantate
flo	uphenazine

Health

	ELLIDUENAZINE DECANOATE
nter contrate contrat	FLUPHENAZINE DECANOATE
	fluphenazine decanoate
	FLUPHENAZINE HYDROCHLORIDE
	Fluphenazine
	FLUPHENAZINE
	haloperidol
	Haloperidol Decanoate
	Haloperidol HALOPERIDOL LACTATE
	haloperidol decanoate
	haloperidol decanoate haloperidol 2mg/ml
	HALOPERIDOL
	HALOPERIDOL DECANOATE
	haloperidol lactate
	HALOPERIDOL? ILOPERIDONE
	Paliperidone
	Paliperidone Palmitate
	paliperidone
	PALIPERIDONE
	lurasidone
	Lurasidone
	Lurasidone Hydrochloride
	lurasidone hydrochloride
	LURASIDONE
	LURASIDONE HYDROCHLORIDE
	Lurasidone hydrochloride
	LEVOMEPROMAZINE
	Levomepromazine Maleate LEVOMEPROMAZINE EMBONATE
	Levomepromazine Embonate
	LEVOMEPROMAZINE HYDROCHLORIDE
	levomepromazine embonate
	levomepromazine hydrochloride
	LEVOMEPROMAZINE MALEATE
	Levomepromazine Hydrochloride
	levomepromazine maleate
	levomepromazine
	Levomepromazine
	methotrimeprazine
	methotrimeprazine hydrochloride
	Periciazine
	PERICIAZINE MECHATE
	PERICIAZINE MESILATE
	periciazine PROPERICIAZINE
	PROPERICIAZINE study-drug-planzanine
	study-drug-olanzapine
	Olanzapine Pamoate

	OLANZAPINE HYDROCHLORIDE
	olanzapine
	OLANZAPINE EMBONATE
	Olanzapine
	OLANZAPINE? ZIPRASIDONE
Land Control of the C	olanzapine embonate
	OLANZAPINE
	Olanzapine Embonate
	pimozide Pimozide
	PIMOZIDE
	prochlorperazine
	Prochlorperazine Maleate
	PROCHLORPERAZINE
	prochlorperazine mesilate
	Prochlorperazine Edisylate
	prochlorperazine mesylate
	Prochlorperazine
	PROCHLORPERAZINE MESILATE
	prochlorperazine hydrochloride
	prochlorperazine maleate
	PROCHLORPERAZINE EDISYLATE PROCHLORPERAZINE MALEATE
	prochlorperazine edisylate PROMAZINE HYDROCHLORIDE
	TRIFLUPROMAZINE
	promazine
	triflupromazine
	PROMAZINE
	ACEPROMAZINE MALEATE
	Promazine Hydrochloride
	ACEPROMAZINE
	triflupromazine hydrochloride
	Promazine
	promazine hydrochloride
	acepromazine acepromazine maleate
	RISPERIDONE
	(RISPERIDONE
	risperidone
	RISPERIDONE NON-COMPANY IMP
	Risperidone
	amisulpride
	AMISULPRIDE
	Amisulpride
	TRIFLUOPERAZINE
	Trifluoperazine Hydrochloride
	TRANYLCYPROMINE SULFATE? TRIFLUOPERAZIN TRIFLUOPERAZINE/TRIFLUOPERAZINE HYDROCHI
	TRIFLUOPERAZINE/TRIFLUOPERAZINE HYDROCHI TRIFLUOPERAZINE HYDROCHLORIDE
	TAIL LOOF LANZINE THE DIAGONILONIDE

	trifluoperazine trifluoperazine hydrochloride DESVENLAFAXINE SUCCINATE MONOHYDRATE desvenlafaxine Desvenlafaxine Desvenlafaxine succinate desvenlafaxine succinate desvenlafaxine succinate desvenlafaxine succinate monohydrate DESVENLAFAXINE Desvenlafaxine Succinate desvenlafaxine Succinate desvenlafaxine Succinate desvenlafaxine Succinate
Dosage Form	All
Route of Administration	All
ATC	All
ATC Pattern	All
Reaction PTs	Assisted suicide Columbia suicide severity rating scale abnormal Completed suicide Depression suicidal Intentional overdose Intentional self-injury Poisoning deliberate Self-injurious ideation Suicidal behaviour Suicidal ideation Suicide attempt Suspected suicide attempt Suspected suicide

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

MedDRA Version:

Report Runtime: 2022-02-15 2:52 PM Total Number of Reports: 12
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

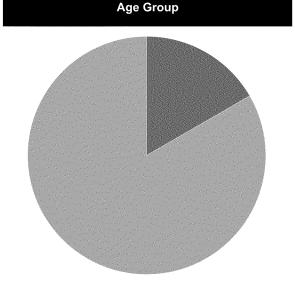
Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousn	ess
			Death	12
		12	Life Threatening	2
69	12		Hospitalization required	2
00	1 6		Disability	0
			Congenital Anomaly	0
			Other Medically	4

Age Group					
ADOLES CENT	2	16.67%			
ADULT	10	83.33%			

	Patient Sex	
Female	4	33.33%
Male	8	66.67%



M ADOLESCENT M ADULT

The Definition for age groups has been taken from the International Conference on Harmonization (ICH) and have been defined as follows:

- Neonate greater than zero and up to 27 days, inclusively
- Infant greater than 27 days and less than 2 years
- Child greater or equal to 2 and less than 12 years
- Adolescent greater or equal to 12 and less than 19 years
- Adult greater or equal to 19 and less than 65 years
- Elderly greater or equal to 65 years

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-15 2:52 PMTotal Number of Reports:12Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

System Organ Class	Number of All Reactions*	Reactions* (% of total)	Number of Reactions* where outcome of AR report was fatal
Cardiac disorders	8	11.59%	4
Gastrointestinal disorders	2	2.90%	1
General disorders and administration site conditions	10	14.49%	6
Hepatobiliary disorders	8	11.59%	4
Injury, poisoning and procedural complications	9	13.04%	5
Investigations	2	2.90%	1
Musculoskeletal and connective tissue disorders	2	2.90%	1
Nervous system disorders	7	10.14%	4
Psychiatric disorders	19	27.54%	8
Respiratory, thoracic and mediastinal disorders	2	2.90%	1
Total Number of Reactions	69	100.00%	35

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 2:52 PM Total Number of Reports: 12 Health Product: See Search Criteria Αll Age: Health Product Role: Gender: All MedDRA Version:

Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

System Organ Class			Number of		
HLGT		Number of All Reactions*	Reactions* where outcome of report was fatal		
HLT	PT	Tredutions			
Cardiac disorders					
Cardiac arrhythmias					
Ventricular arrhythmias and cardiac arrest	Cardiac arrest	2	2		
Heart failures					
Heart failures NEC	Heart failures NEC Cardiac failure				
Myocardial disorders					
Noninfectious myocarditis	Myocarditis	2	2		
Pericardial disorders					
Pericardial disorders NEC	Pericardial effusion	2	2		
	Cardiac disorders SOC Total	8	8		
	Ouraido disordors 500 Fotal				
Gastrointestinal disorders					
Gastrointestinal signs and symptoms					
Nausea and vomiting symptoms	Nausea	2	2		
	Gastrointestinal disorders SOC Total	2	2		



Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-15 2:52 PMTotal Number of Reports:12Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Health Product Role:	Gender		All	
Seriousness: All		A Version:		
nitial Date of Receipt: 2021-01-01 to 2021-1	2-31 Foreign	or Domestic:	Dome	estic
General disorders and administration	site conditions			
Fatal outcomes				
Death and sudden death	Death		1	1
Death and Sudden death	Hanging		1	1
General system disorders NEC				
General signs and symptoms NEC	Multiple organ dysfunction syndrome		2	2
Oedema NEC	Face oedema		2	2
Gederna NEC	Oedema peripheral		2	2
Therapeutic and nontherapeutic effects (exc Therapeutic and nontherapeutic responses	Treatment noncompliance		2	2
General disorders and admin	istration site conditions SO	C Total	10	10
Hepatobiliary disorders Hepatic and hepatobiliary disorders				
Hepatic failure and associated disorders	Hepatic failure		2	2
Hepatic vascular disorders	Congestive hepatopathy		2	2
Hepatocellular damage and hepatitis NEC	Hepatitis		2	2
NEO	Liver injury		2	2
	Hepatobiliary disorders SO	C Total	8	8

*It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this
summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist
and consumer).



Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-15 2:52 PM Total Number of Reports: 12 Health Product: See Search Criteria Age: ΑII Health Product Role: ΑII Gender: Seriousness: MedDRA Version: Foreign or Domestic: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Domestic Injury, poisoning and procedural complications Exposures, chemical injuries and poisoning 3 Poisoning and toxicity 3 Toxicity to various agents Injuries by physical agents Thermal burns 1 1 Thermal burn Overdoses and underdoses NEC 2 2 Intentional overdose Overdoses NEC 2 2 Overdose Underdoses NEC 1 1 Underdose Injury, poisoning and procedural complications SOC Total 9 9 Investigations Metabolic, nutritional and blood gas investigations 2 2 Blood gas and acid base analyses Oxygen saturation decreased **Investigations SOC Total** 2 2 Musculoskeletal and connective tissue disorders Muscle disorders 2 2 Muscle pains Myalgia

Musculoskeletal and connective tissue disorders SOC Total



2

2

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM Total Number of Reports: 12 All Health Product: See Search Criteria Age: Health Product Role: ΑII Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Nervous system disorders Central nervous system vascular disorders Central nervous system haemorrhages 1 1 and cerebrovascular accidents Cerebrovascular accident Encephalopathies Encephalopathies NEC 2 2 Encephalopathy 2 2 Encephalopathies toxic and metabolic Hepatic encephalopathy Seizures (incl subtypes) Seizures and seizure disorders NEC 2 2 Seizure **Nervous system disorders SOC Total** 7 7

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

Health

Report Runtime:

Canada

2022-02-15 2:52 PM

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12

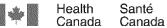
Canada Vigilance Summary of Product Adverse Reactions

Total Number of Reports:

Health Product: See Search Criteria Age: ΑII Health Product Role: ΑII Gender: MedDRA Version: Seriousness: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Psychiatric disorders Anxiety disorders and symptoms 2 2 Anxiety symptoms Agitation Disturbances in thinking and perception Delusional symptoms 1 1 Delusion of reference Personality disorders and disturbances in behaviour Behaviour and socialisation disturbances 1 1 Aggression Schizophrenia and other psychotic disorders 1 1 Psychotic disorder NEC Psychotic disorder Sleep disorders and disturbances Disturbances in initiating and maintaining 1 1 sleep Insomnia Suicidal and self-injurious behaviours NEC 1 1 Assisted suicide Suicidal and self-injurious behaviour 11 11 Completed suicide Suicidal ideation 1 1 **Psychiatric disorders SOC Total** 19 19 Respiratory, thoracic and mediastinal disorders Pleural disorders Pneumothorax and pleural effusions NEC 2 2 Pleural effusion Respiratory, thoracic and mediastinal disorders SOC Total 2 2

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).





Canada Vigilance Summary of Product Adverse Reactions Santé Canada

MedDRA Version:

Report Runtime: 2022-02-15 2:52 PM Total Number of Reports: 12 Health Product: See Search Criteria Αll Age: Health Product Role: Gender: All

Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic



Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

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Report Runtime: 2022-02-15 2:52 PM
Health Product: See Search Criteria

See Search Criteria Age:
Gender:

Seriousness: All

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

12

All

ΑII

			2021							History Co.						
		Jan	uary	Febr	uary	Mai	rch	Ar	oril	Ma	ay	Ju	ne	Septe	mber	October
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Cardiac arrest	GR-500		1	1.1							- 1	1/2	74.52		
	Cardiac failure			1	1							1	1			
Cardiac disorders	Myocarditis		13	1	1		5;					1				
	Pericardial effusion			1	1							1	1			
	SOC Subtotal			4	4							4	4			
			1	1	1					,		1		1	1	
Gastrointestinal disorders	Nausea			1	_1	J						1	_1			
	SOC Subtotal			1	1							1	1			



Report Runtime:2022-02-15 2:52 PMTotal Number of Reports:12Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

			20	21		
			Nove	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Cardiac arrest				2	2
	Cardiac failure				2	2
Cardiac disorders	Myocarditis		13		2	2
	Pericardial effusion				2	2
	SOC Subtotal				8	8

Gastrointestinal disorders	Nausea		2	2
	SOC Subtotal		2	2



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Report Runtime: 2022-02-15 2:52 PM Total Number of Reports: 12
Health Product: See Search Criteria Age: All

Health Product Role: Gender:
Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

							500 5 (1994)	200	2021							
		Jan	uary	Febr	uary	Ma	rch	Ar	oril	М	ay	Ju	ine	Septe	ember	October
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Death															
	Face oedema				1							1	1			
General disorders and administration site	Hanging					1	1					1				
conditions	Multiple organ dysfunction syndrome											1	1			
	Oedema peripheral			1	1							1	1			
	Treatment noncompliance				1							1	1			
	SOC Subtotal			4	4	1	1					4	4			
	Congestive hepatopathy			1	1							1	1			
Hepatobiliary disorders	Hepatic failure			2,15	1		ورون دومس ورونو					(c) 1 ;	1,500			
	Hepatitis			1	1							1	1			
	Liver injury	53	535	0.172	<u>(192</u>		<u> </u>	55	(3.,			0.100	10.190			
	SOC Subtotal			4	4							4	4			

ΑII



Report Runtime: 2022-02-15 2:52 PM Health Product: See Search Criteria

ΑII

Total Number of Reports: 12 All Age: Gender: ΑII

Health Product Role:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

MedDRA Version:

Foreign or Domestic: Domestic

2021 November Total Outcome All Outcome Total All soc PT Outcome Fatal Reactions Reactions Fatal Fatal 1 1 Death 2 2 Face oedema 1 1 Hanging General disorders and administration site conditions 2 2 Multiple organ dysfunction syndrome 2 2 Oedema peripheral 2 Treatment 2 noncompliance **SOC Subtotal** 1 10 10 Congestive 2 2 hepatopathy Hepatic failure 2 2 Hepatobiliary disorders 2 2 Hepatitis Liver injury 2 2 **SOC Subtotal** 8



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Report Runtime: 2022-02-15 2:52 PM Total Number of Reports:

Health Product: See Search Criteria Age:
Health Product Role: Gender:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

			89					1	2021							
		Jan	uary	Febr	uary	Ma	rch	Ap	ril	Ma	ay	Ju	ne	Septe	mber	October
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Intentional overdose			1	1							1	1			
	Overdose			1	1							1	1			
Injury, poisoning and procedural complications	Thermal burn															
	Toxicity to various agents			1								1				
	Underdose															1
	SOC Subtotal			3	3			1	1			3	3			1
Investigations	Oxygen saturation decreased			11	1					} };		1	(- 1 ,			
	SOC Subtotal			1	1							1	1			
Musculoskeletal and connective tissue disorders	Myalgia			1	1							1	1			
	SOC Subtotal			1	1							1	1			

12

All

ΑII



Report Runtime: 2022-02-15 2:52 PM
Health Product: See Search Criteria

Total Number of Reports: 12
Age: All
Gender: All

Health Product Role:

Gender: MedDRA Version:

Seriousness: All

E : B : :

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

			20	21		
			Nove	mber		
SOC	PT .	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Intentional overdose				2	2
	Overdose				2	2
Injury, poisoning and procedural complications	Thermal burn		1	1	1	1
	Toxicity to various agents				3	3
	Underdose	1			1	1
	SOC Subtotal	1	1	1	9	9
Investigations	Oxygen saturation decreased				2	2
	SOC Subtotal				2	2
Musculoskeletal and connective tissue disorders	Myalgia				2	2
	SOC Subtotal				2	2



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Report Runtime: 2022-02-15 2:52 PM Total Number of Reports: 12
Health Product: See Search Criteria Age: All

Health Product Role: Gender:
Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

									2021							
		Jan	uary	Febr	ruary	Ma	rch	Ar	oril	M	ay	Ju	ne	Septe	ember	October
soc	PT PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Cerebrovascular accident					1	1									
Nervous system	Encephalopathy			1	1							1	1			
lisorders	Hepatic encephalopathy			101	101		305	7.7.7. 7.7.7.7.				1	13			
	Seizure			1	1							1	1			
	SOC Subtotal			3	3	1	1					3	3			
	Aggression	1	: J1													
	Agitation			1	1	1.00						1	1		1	
	Assisted suicide	11:				1	1									3
	Completed suicide	1	1	1	1	1	1	1	1	1	1	2	2	1	1	1
sychiatric disorders	Delusion of reference						6.57									
	Insomnia	1	1													
	Psychotic disorder	1::-1::-														
	Suicidal ideation	1	1													
961 VA QL	SOC Subtotal	5	5	2	2	2	2	1	1	1	1	3	3	1	1	1
tespiratory, thoracic nd mediastinal isorders	Pleural effusion							3		5.0		361		310		
	SOC Subtotal		1.2.2.2.2.2	1	1	N. 178.27						1	1	1000		

ΑII



Report Runtime: 2022-02-15 2:52 PM
Health Product: See Search Criteria

Total Number of Reports: 12 Age: All

Health Product Role:

Gender:

Seriousness: Initial Date of Receipt: All 2021-01-01 to 2021-12-31

MedDRA Version:

Foreign or Domestic: Domestic

ΑII

			20	21		
			Nove	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Cerebrovascular accident				1	1
Nervous system	Encephalopathy				2	2
disorders	Hepatic encephalopathy				2	2
	Seizure				2	2
	SOC Subtotal				7	7

	Aggression				1	1
	Agitation				2	2
	Assisted suicide				1	1
Barrakitakita dia andara	Completed suicide	1	2	2	11	11
Psychiatric disorders	Delusion of reference		4.45	7.7 1	1	1
	Insomnia				1	1
	Psychotic disorder				1	1
	Suicidal ideation				1	1
	SOC Subtotal	1	3	3	19	19

Respiratory, thoracic and mediastinal disorders	Pleural effusion		2	2
	SOC Subtotal		2	2



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Report Runtime: 2022-02-15 2:52 PM Total Number of Reports:
Health Product: See Search Criteria Age:

Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

			2021													
		Jan	uary	Febr	uary	Ma	rch	Aŗ	oril	М	ay	Ju	ne	Septe	mber	October
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Grand Total	5	5	24	24	4	4	2	2	1	1	25	25	1	1	2

12



Report Runtime:2022-02-15 2:52 PMTotal Number of Reports:12Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

			20	21		
			Nove	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Grand Total	2	5	5	69	69



Report Runtime: 2022-02-15 2:52 PM Health Product: See Search Criteria

ΑII

12 All Age: Gender: ΑII

Health Product Role:

Total Number of Reports:

Seriousness:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		20	21		
soc	PT	All Outs			Total Outcome Fatal
	Cardiac arrest	2	2	2	2
Cardiac disorders	Cardiac failure	2	2	2	2
Cardiac disorders	Myocarditis	2	2	2	2
	Pericardial effusion	2	2	2	2
	SOC Subtotal	8	8	8	8
Gastrointestinal disorders	Nausea	2	2	2	2
	SOC Subtotal	2	2	2	2
	Death	1	1	1	1
	Face oedema	2	2	2	2
General disorders	Hanging	1	1	1	1
site conditions	Multiple organ dysfunction syndrome	2	2	2	2
	Oedema peripheral	2	2	2	2
	Treatment noncompliance	2	2	2	2
	SOC Subtotal	10	10	10	10



Report Runtime: 2022-02-15 2:52 PM Total Number of Reports:
Health Product: See Search Criteria Age:
Health Product Role: Gender:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		20	21	97.35	
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Congestive hepatopathy	2	2	2	2
Hepatobiliary	Hepatic failure	2	2	2	2
disorders	Hepatitis	2	2	2	2
	Liver injury	2	2	2	2
	SOC Subtotal	8	8	8	8
	Intentional overdose	2	2	2	2
	Overdose	2	2	2	2
Injury, poisoning and procedural complications	Thermal burn	1	1	1	1
	Toxicity to various agents	3	3	3	3
	Underdose	1	1	1	1
	SOC Subtotal	9	9	9	9
Investigations	Oxygen saturation decreased	2	2	2	2
	SOC Subtotal	2	2	2	2

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12

All

ΑII



Report Runtime: 2022-02-15 2:52 PM Health Product: See Search Criteria

All

12 All Age: Gender: ΑII

Total Number of Reports:

Health Product Role:

MedDRA Version:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		2021			
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Musculoskeletal and connective tissue disorders	Myalgia	2	2	2	2
	SOC Subtotal	2	2	2	2
	Cerebrovascular accident	5 1	37. 1	1	1
Nervous system	Encephalopathy	2	2	2	2
disorders	Hepatic encephalopathy	2	2	2	2
	Seizure	2	2	2	2
	SOC Subtotal	7	7	7	7



Report Runtime: 2022-02-15 2:52 PM Health Product: See Search Criteria

12 Total Number of Reports: All Age: ΑII

Health Product Role:

Gender:

All Seriousness:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		2021			
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Aggression	1	1 1	1	1
	Agitation	2	2	2	2
	Assisted suicide	\$5.15E	1 /-	1	1
Psychiatric	Completed suicide	11	11	11	11
disorders	Delusion of reference	12 - 12 - 12 - 12 - 12 - 12 - 12 - 12 -	1	1	1
	Insomnia	1	1	1	1
	Psychotic disorder	1	1 1 1 1 1	1	1
	Suicidal ideation	1	1	1	1
	SOC Subtotal	19	19	19	19
Respiratory, thoracic and mediastinal disorders	Pleural effusion	2	2	2	2
	SOC Subtotal	2	2	2	2
	Grand Total	69	69	69	69

ATI-2021-001920

From January 1st, 2021 to December 31st, 2021, Health Canada's Canada Vigilance Program has received **35** fatal **domestic** adverse reaction (AR) reports with suspected **"Mood Stabilizer"** products listed below.

"Carbamazepine / Tegretol, Divalproex Sodium, Lamotrigine, Lithium, Valproic acid, Depakote, Depakene".

From January 1st, 2021 to December 31st, 2021, Health Canada's Canada Vigilance Program has received **32** fatal **domestic** adverse reaction (AR) reports with suspected **"Stimulant"** products listed below.

"Adderall / dextroamphetamine and amphetamine, Concerta / methylphenidate, Daytrana, Dexedrine / dextroamphetamine, Focalin / dexmethylphenidate, Metadate, Methylin, Ritalin, Vyvanse / Lisdexamfetamine, Dyanavel / Amphetamine Sulfate, Evekeo, Mydayis, Aptensio, Cotempla, Quillichew, Quillivant, Azstarys / serdexmethylphenidate and dexmethylphenidate".

Please note the following caveats:

- It is often not possible to determine whether an adverse reaction reported to Health Canada is a result of using a specific health product. Other factors contributing to the reaction could be a person's health conditions or other health products they are using at the same time.
- Adverse reaction reports are suspected associations and reflect the opinion or observation of the individual reporter. The data do not reflect any Health Canada assessment of association between the health product and the reaction(s).
- Please consult the following <u>link</u> for additional caveats on the interpretation of suspected adverse reaction data collected by the Canada Vigilance program.

Page: 1 of/de 62 A2021001920



Search Criteria

Report Runtime:	2022-02-16 - 9:29 AM 2.92 minutes
Range for Initial Date Received	2021-01-01 to 2021-12-31
AER No(s)	
Country of Occurence	Domestic
Case Serious?	All
Case Outcome	Fatal
Report Source	All
Patient Gender	All
Range for Age (years)	All
Reporter Type	All
Source Company Unit	All
Product Role	
Product Class	All
Product Description	All
DIN/NPN	
	diethylcarbamazine citrate CARBAMAZEPINE carbamazepine DIETHYLCARBAMAZINE CITRATE Carbamazepina diethylcarbamazine Carbamazepine divalproex sodium valproic acid (divalproex sodium) DIVALPROEX SODIUM LAMOTRIGINE lamotrigine LAMOTRIGIN Lamotrigine LITHIUM Lithium orotate LITHIUM SULFATE

CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement. (10/2007).



Glossary/Abbreviations

Term	Definition	
Age	Age of the patient when the adverse reaction reports and age specific search will be searched with the specific search will be searched with the search of t	е
AR	Adverse Reaction Lithium Acetate lithium succinate	
Gender	Gender of the patient as it was provided by the reporter. The gender is unknown in some of the adreaction reports and gender specific seathers wan ponate and gender is unknown	verse I.
Health Product	Ingredient(s) A health product includes drugs and prescription pharmaceuticals; biotechnology products and biologically-derived products such as vaccines, serums, and blood derived products distinfectants; and radiopharmaceuticals.	ion-
Health Product Role	The characterization of the role of the lighteduc salfatevided by the original reporter of the adverse reaction. The health product role replies the parties on, opinion or observation of the individual reporter. Cause and effect relationship to the product cause of the health product cause the health product cause the health product was not suspected by the parties are reaction. A 'concomitant' role indicates the health product was not suspected by the parties are reaction. Lithium Aspartate	that
HLT	High Level Term – see definition of Methira gluconate	
HLGT	LITHIUM BROMIDE High Level Group Term – see definition PHMMOBROTATE	
Initial Date of Receipt	The date that the first version of the Vigilance Program. Lithium adverse reaction report was received by Health Canada's Can CARBONATE DE LITHIUM lithium citrate	ada
MedDRA	Medical Dictionary for Regulatory Activities Media A is an internationally recognized standardize of terms used to facilitate the regulation of the professional process and adverse reacterms in a hierarchical structure whereby the 'preferred term' (PT) is grouped under the broader he of 'high level term' (HLT). 'High level terms' are then grouped under 'high level group terms (HLGT) which are then grouped by 'system organiciass' (SOC). The 'preferred term' is the most specific terms are then grouped by 'system organiciass' (SOC).	tion
MedDRA Version	valproic acid The MedDRA terminology is updated valapacoants sold யூரி நக்கட் பிரையில் version displated valapacoants.	yed
NEC	Not Elsewhere Classified – MedDRA Valproic acid VALPROIC ACID	
NOS Dosag	Not Otherwise Specified – MedDRA abbreviation All	
-	Preferred Term – A MedDRA Preferred Term is an adverse reaction term which is a distinct description of Adjaninistration of the property of the preferred Term is an adverse reaction term which is a distinct description of the preferred Term is an adverse reaction term which is a distinct description of the preferred Term is an adverse reaction term which is a distinct description.	
ATC	surgical or medical procedure, and medical, social, or family history characteristic. All	
	The seriousness of the adverse reaction report is based on the following reasons: an adverse reaction atterned in-patient hospitalization (A) a prolongation of existing hospitalization, that causes concentration, that results in persistent or significent dischility, that is life threatening, that results in our Prenicted a medically important the provided in the p	genital
soc	System Organ Class – A System Organ Class is the highest level of the hierarchy that provides the broadest concept for data retrieval. Each adverse reaction term is assigned one primary SOC.)



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Canada Vigilance Summary of Product Adverse Reactions

MedDRA Version:

Report Runtime:2022-02-16 9:29 AMTotal Number of Reports:35Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

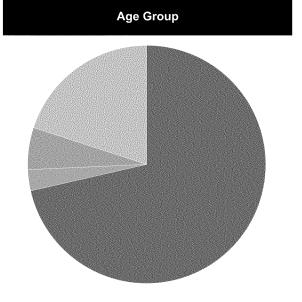
Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousn	ess
			Death	35
156	35	35	Life Threatening	1
			Hospitalization required	4
100			Disability	3
			Congenital Anomaly	0
			Other Medically	26

	Age Group	
ADULT	25	71.43%
CHILD	1	2.86%
ELDERLY	2	5.71%
UNKNOW N	7	20.00%

	Patient Sex	
Female	11	31.43%
Male	24	68.57%



M ADULT ■ CHILD ■ ELDERLY ■ UNKNOWN

The Definition for age groups has been taken from the International Conference on Harmonization (ICH) and have been defined as follows:

- Neonate greater than zero and up to 27 days, inclusively
- Infant greater than 27 days and less than 2 years
- Child greater or equal to 2 and less than 12 years
- Adolescent greater or equal to 12 and less than 19 years
- Adult greater or equal to 19 and less than 65 years
- Elderly greater or equal to 65 years

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

2022-02-16 9:29 AM Report Runtime: Total Number of Reports: 35 Health Product: See Search Criteria All Age: Health Product Role: Gender: All MedDRA Version:

Seriousness:

Health

Canada

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

System Organ Class	Number of All Reactions*	Reactions* (% of total)	Number of Reactions* where outcome of AR report was fatal
Blood and lymphatic system disorders	3	1.92%	3
Cardiac disorders	5	3.21%	4
Eye disorders	1	0.64%	1
Gastrointestinal disorders	1	0.64%	1
General disorders and administration site conditions	37	23.72%	11
Infections and infestations	4	2.56%	2
Injury, poisoning and procedural complications	20	12.82%	11
Investigations	12	7.69%	9
Nervous system disorders	33	21.15%	15
Psychiatric disorders	25	16.03%	5
Respiratory, thoracic and mediastinal disorders	8	5.13%	6
Skin and subcutaneous tissue disorders	2	1.28%	2
Social circumstances	4	2.56%	1
Vascular disorders	1	0.64%	1
Total Number of Reactions	156	100.00%	72

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-16 9:29 AMTotal Number of Reports:35Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

System Organ Class			Number of	
HLGT		Number of All Reactions*	Reactions* where outcome	
HLT	[PT		of report was fatal	
Blood and lymphatic system disord	ders			
Coagulopathies and bleeding diatheses (excl thrombocytopenic)			
Coagulopathies	Disseminated intravascular coagulation	1	1	
Platelet disorders				
Thrombocytopenias	Thrombocytopenia	1	1	
		1		
White blood cell disorders				
Leukocytoses NEC	Leukocytosis	1	1	
Blood and ly	mphatic system disorders SOC Total	3	3	

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

2022-02-16 9:29 AM

Report Runtime:

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35

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Total Number of Reports:

Health Product: See Search Criteria Age: Αll Health Product Role: Αll Gender: MedDRA Version: Seriousness: Foreign or Domestic: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Domestic Cardiac disorders Cardiac arrhythmias Ventricular arrhythmias and cardiac 2 2 arrest Ventricular arrhythmia Cardiac valve disorders Mitral valvular disorders 1 1 Mitral valve incompetence **Heart failures** 1 1 Heart failures NEC Cardiac failure Myocardial disorders Noninfectious myocarditis 1 Myocarditis 1 Cardiac disorders SOC Total 5 5 Eye disorders Ocular neuromuscular disorders 1 1 Ocular nerve and muscle disorders Eye movement disorder 1 1 Eye disorders SOC Total **Gastrointestinal disorders** Gastrointestinal signs and symptoms Nausea and vomiting symptoms 1 1 Vomiting 1 **Gastrointestinal disorders SOC Total** 1

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



Canada Vigilance Summary of Product Adverse Reactions Santé Canada

2022-02-16 9:29 AM Report Runtime: Total Number of Reports: 35 Health Product: See Search Criteria All Age: Health Product Role: Gender: All

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Seriousness:	All	Me	dDRA Version:		
Initial Date of Receipt:	nitial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domes		eign or Domestic:	estic: Domestic	
General disorders	and administration si	te conditions			
Body temperature co	nditions				
Febrile disorders		Pyrexia		1	1
Fatal outcomes					
		Accidental death		4	4
Death and sudden death	death	Death		3	3
		Sudden unexplained death epilepsy	in	1	1
General system disor	rders NEC				
Asthenic condition	s	Malaise		2	2
General signs and	symptoms NEC	Unmasking of previously unidentified disease		2	2
Pain and discomfo	rt NEC	Chest pain		1	1
		-			
Therapeutic and non	therapeutic effects (excl to	xicity)			
		Drug interaction		18	18
Interactions		Food interaction		2	2

herapeutic and nontherapeutic effects (e	excl toxicity)		
	Drug interaction	18	18
Interactions	Food interaction	2	2
	Potentiating drug interaction	2	2
Therapeutic and nontherapeutic responses	Multiple-drug resistance	1	1

General disorders and administration site conditions SOC Total	37	37

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-16 9:29 AMTotal Number of Reports:35Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Infections - pathogen unspecified			
Cardiac infections	Endocarditis	1	1
Lower respiratory tract and lung infections	Pneumonia	3	3

Infections and infestations SOC Total	4	4
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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

2022-02-16 9:29 AM Total Number of Reports: Report Runtime: 35 Health Product: See Search Criteria All Age: Health Product Role: Gender: All

MedDRA Version: Seriousness: All

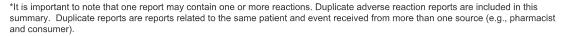
Initial Date of Receipt: 2021-01-01 to 2021-12	2-31 Foreign or Domest	tic: Don	Domestic	
Injury, poisoning and procedural complications Exposures, chemical injuries and poisoning				
Poisoning and toxicity	Toxicity to various agents	4	4	
Injuries NEC				
Skin injuries NEC	Skin injury	1	1	
Medication errors and other product use erro	rs and issues			
Medication errors, product use errors and issues NEC	Product use in unapproved indication	2	2	
Product administration errors and issues	Failure to suspend medication	2	2	
	Incorrect route of product administration	1	1	
	Product dose omission issue	1	1	
	Wrong patient received product	2	2	
Product monitoring errors and issues	Labelled drug-drug interaction issue	2	2	
Off label uses and intentional product misuse	es/use issues			
Intentional product use issues	Intentional product use issue	2	2	

Off label uses and intentional product misuses/use issues			
Intentional product use issues	Intentional product use issue	2	2

Overdoses and underdoses NEC			
Overdoses NEC	Intentional overdose	1	1
	Prescribed overdose	2	2

Injury, poisoning and procedural complications SOC Total	20	20

2022-02-16 9:29 AM Total Number of Reports: Report Runtime: 35 Health Product: See Search Criteria Age: All Αll Health Product Role: Gender: MedDRA Version: Seriousness: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Investigations Cardiac and vascular investigations (excl enzyme tests) 2 2 ECG investigations Electrocardiogram QT prolonged **Enzyme investigations NEC** Blood creatine phosphokinase Skeletal and cardiac muscle analyses 1 1 increased Haematology investigations (incl blood groups) 1 1 Red blood cell analyses Haemoglobin decreased 1 1 Neutrophil count increased White blood cell analyses 1 1 White blood cell count increased Hepatobiliary investigations 1 Liver function analyses 1 Ammonia increased Toxicology and therapeutic drug monitoring Antidepressant drug level above 2 2 therapeutic Therapeutic drug monitoring analyses 1 1 Antipsychotic drug level increased 2 2 Toxicology laboratory analyses Postmortem blood drug level **Investigations SOC Total** 12 12 Nervous system disorders Central nervous system vascular disorders Central nervous system vascular 2 2 disorders NEC Cerebral amyloid angiopathy Increased intracranial pressure and hydrocephalus 1 1 Increased intracranial pressure disorders Brain oedema





Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-16 9:29 AMTotal Number of Reports:35Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Alzheimer's disease (incl subtypes)	Dementia Alzheimer's type	2	2
Mental impairment (excl dementia and memory loss)	Mental impairment	2	2
	'		

Movement disorders (incl parkinsonism)			
Dyskinesias and movement disorders NFC	Dyskinesia	2	2
NEO	Tardive dyskinesia	2	2
Parkinson's disease and parkinsonism	Parkinsonism	2	2

Neurological disorders NEC			
Disturbances in consciousness NEC	Lethargy	1	1
Disturbances in consciousness NEC	Somnolence	2	2
N	Dizziness	6	6
Neurological signs and symptoms NEC	Unresponsive to stimuli	7	7

Neuromuscular disorders			
Muscle tone abnormal	Hypotonia	1	1

Seizures (incl subtypes)			
Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	1	1
Seizures and seizure disorders NEC	Status epilepticus	1	1

Spinal cord and nerve root disorders			
Spinal cord and nerve root disorders NEC	Myelopathy	1	1

	Nervous system disorders SOC 1	otal 33	33
--	--------------------------------	---------	----

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:29 AM Total Number of Reports: 35 Αll Health Product: See Search Criteria Age: Health Product Role: All Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Psychiatric disorders Deliria (incl confusion) Confusion and disorientation 4 4 Confusional state Depressed mood disorders and disturbances Depressive disorders 16 16 Depression Disturbances in thinking and perception Hallucinations (excl sleep-related) 2 2 Hallucination Psychiatric disorders NEC Substance related and addictive 2 2 disorders Drug abuse Suicidal and self-injurious behaviours NEC Suicidal and self-injurious behaviour 1 1 Suicide attempt

Psychiatric disorders SOC Total

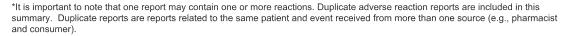
25

25

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:29 AM Total Number of Reports: 35 All Health Product: See Search Criteria Age: Health Product Role: ΑII Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Respiratory, thoracic and mediastinal disorders Lower respiratory tract disorders (excl obstruction and infection) 1 Parenchymal lung disorders NEC 1 Atelectasis Pulmonary vascular disorders Pulmonary thrombotic and embolic 1 1 conditions Pulmonary embolism Respiratory disorders NEC 2 2 Dyspnoea Breathing abnormalities 2 2 Respiratory depression Respiratory failures (excl neonatal) 1 1 Respiratory failure Respiratory tract signs and symptoms Lower respiratory tract signs and 1 1 symptoms Rales Respiratory, thoracic and mediastinal disorders SOC Total 8 8 Skin and subcutaneous tissue disorders **Epidermal and dermal conditions** 1 1 Stevens-Johnson syndrome **Bullous** conditions 1 1 Toxic epidermal necrolysis



Skin and subcutaneous tissue disorders SOC Total



2

2

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-16 9:29 AM Total Number of Reports: 35 See Search Criteria Αll Health Product: Age: Health Product Role: All Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Social circumstances Lifestyle issues Loss of personal independence in Disability issues 4 4 daily activities Social circumstances SOC Total 4 4 Vascular disorders **Embolism and thrombosis** Peripheral embolism and thrombosis 1 1 Deep vein thrombosis Vascular disorders SOC Total 1 1



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Report Runtime: 2022-02-16 9:29 AM Total Number of Reports: 35
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

ilidal Date of Net	2021-01-01 to		•	***************************************		sign or bo			Jillostio							× × × × × × × × × × × × × × × × × × ×
									2021							
		Febr	uary	Ma	rch	Aŗ	ril	Ma	ay	Ju	ne	Jı	aly	Aug	just	September
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Disseminated intravascular coagulation															
Blood and lymphatic system disorders	Leukocytosis											1	1			
	Thrombocytopenia			<u> </u>							[] - 1					
	SOC Subtotal									1	1	1	1			
	Cardiac failure											1	1			
Cardiac disorders	Mitral valve incompetence											1	1 11			
	Myocarditis											1	1			
	Ventricular arrhythmia		2										<u> </u>	21	1:::: 1 ::::::	<u> </u>
	SOC Subtotal											3	3	1	1	
Eye disorders	Eye movement disorder									1	1					
	SOC Subtotal									1	1					
Gastrointestinal disorders	Vomiting										,1,					
	SOC Subtotal									1	1					
General disorders and administration site conditions	Accidental death							1	1					1	4	



Seriousness:

Canada Vigilance Summary of Product Adverse Reactions

Gender:

MedDRA Version:

Report Runtime: 2022-02-16 9:29 AM Total Number of Reports: Health Product: See Search Criteria Age:

Health Product Role:

All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

					20	21				
			Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Disseminated intravascular coagulation				1	303			1	1
Blood and lymphatic system disorders	Leukocytosis								1	1
	Thrombocytopenia								1	1
	SOC Subtotal				1	1			3	3
	Cardiac failure								1	1
Cardiac disorders	Mitral valve incompetence	55		33	672			33-	1	1
34, 414, 54, 54, 54, 54, 54, 54, 54, 54, 54, 5	Myocarditis								1	1
	Ventricular arrhythmia						11	1	2	2
	SOC Subtotal						1	1	5	5
Eye disorders	Eye movement disorder								1	1
	SOC Subtotal								1	1
Gastrointestinal disorders	Vomiting			7					1	1
	SOC Subtotal								1	1
General disorders and administration site conditions	Accidental death				1	1	1	1	4	4

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35

All

ΑII





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Report Runtime: 2022-02-16 9:29 AM Total Number of Reports:

Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

							100		2021						The second	
		Febr	uary	Ma	rch	Ap	oril	Mi	ay	Ju	ne	Ju	ıly	Aug	just	September
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Chest pain											1	1			
	Death											1	1	1	1	
	Drug interaction	4	4			2	2		1	4	4			2	2	2
	Food interaction													1	1	
General disorders and administration site	Malaise														1	
conditions	Multiple-drug resistance															
	Potentiating drug interaction															
	Pyrexia											1	que			
	Sudden unexplained death in epilepsy															
	Unmasking of previously unidentified disease									1	1					
	SOC Subtotal	4	4			2	2	2	2	5	5	3	3	7	7	2

35



Report Runtime: 2022-02-16 9:29 AM
Health Product: See Search Criteria

All

Age: All

Total Number of Reports:

Health Product Role:

Gender: All

35

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

				11.52	20	21				
			Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Chest pain								1	1
	Death						1	1	3	3
	Drug interaction	2	1	5-1					18	18
	Food interaction						1	1	2	2
General disorders and	Malaise						331		2	2
administration site conditions	Multiple-drug resistance				1	1			1	1
	Potentiating drug interaction								2	2
	Pyrexia								1	1
	Sudden unexplained death in epilepsy								1	1
	Unmasking of previously unidentified disease		1	1					2	2
	SOC Subtotal	2	2	2	4	4	6	6	37	37



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Report Runtime: 2022-02-16 9:29 AM Total Number of Reports: 35
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Initial Date of Re	ceipt: 2021-01-01 to	2021-12-3	1		For	eign or Do	mestic:	D	omestic							
									2021							
		Febr	uary	Ma	rch	Aţ	oril	м	ay	Ju	ne	Ju	ıly	Aug	gust	Septembe
SOC	РТ	All Reactions	Outcome Fatal	All Reactions												
infections and	Endocarditis											1	1			
infestations	Pneumonia									1	1			1	1	
	SOC Subtotal									1	1	1	1	1	1	
	Failure to suspend medication								7/1							
	Incorrect route of product administration															
	Intentional overdose															
injury, poisoning and procedural	Intentional product use issue							1	1							1
procedural complications	Labelled drug-drug interaction issue															
	Prescribed overdose							1	1							1
	Product dose omission issue															
	Product use in unapproved indication															



MedDRA Version:

Report Runtime: 2022-02-16 9:29 AM Total Number of Reports: 35 All Health Product: See Search Criteria Age: Gender: All

All Seriousness:

Health Product Role:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

					20	21				
			Octo	ber	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Infections and	Endocarditis								1	1
infestations	Pneumonia						1	1	3	3
	SOC Subtotal						1	1	4	4

	Failure to suspend medication				5. <u>t</u>	1			2	2
	Incorrect route of product administration		1	1					1	1
	Intentional overdose								1	1
Injury, poisoning and	Intentional product use issue	1							2	2
procedural complications	Labelled drug-drug interaction issue						1	1	2	2
	Prescribed overdose	1							2	2
	Product dose omission issue								1	1
	Product use in unapproved indication		2	2					2	2



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Report Runtime: 2022-02-16 9:29 AM
Health Product: See Search Criteria

Total Number of Reports: 35
Age: All

Health Product Role:

Gender: All

Seriousness: All

MedDRA Version:

Initial Date of Receipt: 26

2021-01-01 to 2021-12-31 Foreign or Do

Foreign or Domestic: Domestic

								-	2021							
		Febr	uary	Ma	rch	Ар	ril	Ma	ay	Ju	ne	Ju	ıly	Aug	ust	September
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Skin injury															
Injury, poisoning and procedural complications	Toxicity to various agents			1	1			1	1			1	1			
	Wrong patient received product															
	SOC Subtotal			1	1			5	5	1	1	1	1	1	1	2



Report Runtime: 2022-02-16 9:29 AM Health Product: See Search Criteria

All

Total Number of Reports: 35

Health Product Role:

All Age: Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

					20	21		P. 06 00 00 00		
			Octo	ober	Nove	mber	Dece	mber		100
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
State of the state	Skin injury				1	1			1	1
Injury, poisoning and procedural complications	Toxicity to various agents				1	1			4	4
	Wrong patient received product					1			2	2
	SOC Subtotal	2	3	3	5	5	1	1	20	20



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Report Runtime:2022-02-16 9:29 AMTotal Number of Reports:35Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

									2021							
		Febr	uary	Ma	rch	A	pril	м	ay	Ju	ne	Jı	aly	Aug	just	September
soc	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Ammonia increased									1	1					
	Antidepressant drug level above therapeutic		G.	<u> </u>			0		0::::::::::::::::::::::::::::::::::::::	Ċ.		<u> </u>	102::::::::::::::::::::::::::::::::::::	3.1	0.1	<u> </u>
	Antipsychotic drug level increased									1	1					
	Blood creatine phosphokinase increased	11														
Investigations	Electrocardiogram QT prolonged													1	1	
	Haemoglobin decreased									1						
	Neutrophil count increased											1	1			
	Postmortem blood drug level														319	
	White blood cell count increased											1	1			
2) Since disapare disapare disapare	SOC Subtotal									4	4	2	2	3	3	
	Brain oedema									_1	1					
Nervous system	Cerebral amyloid angiopathy									1	1					
disorders	Dementia Alzheimer's type															
	Dizziness			4	4											



Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

Gender:

ΑII

Report Runtime: 2022-02-16 9:29 AM Total Number of Reports: 35
Health Product: See Search Criteria Age: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

					20	21		100		
			Octo	ber	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Ammonia increased								1	1
	Antidepressant drug level above therapeutic				Q.		Q	1	2	2
	Antipsychotic drug level increased								1	1
	Blood creatine phosphokinase increased								1	1
Investigations	Electrocardiogram QT prolonged						1	1	2	2
	Haemoglobin decreased								1	1
	Neutrophil count increased								1	1
	Postmortem blood drug level							1.1	2	2
	White blood cell count increased								1	1
en e	SOC Subtotal						3	3	12	12
	Brain oedema								1	1
Nervous system	Cerebral amyloid angiopathy		1	1					2	2
disorders	Dementia Alzheimer's type		1	1/1					2	2
	Dizziness				2	2			6	6





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Report Runtime: 2022-02-16 9:29 AM
Health Product: See Search Criteria

Health Product Role:

Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 35

Age: All Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

								40	2021						Harry Co.	
		Febi	ruary	Ma	rch	Aţ	oril	M	ay	Ju	ne	Ju	ily	Aug	just	September
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Dyskinesia									1	10					
	Generalised tonic- clonic seizure															
	Hypotonia									5.1						
	Lethargy															
	Mental impairment								3240					1		
Nervous system disorders	Myelopathy									1	1					
	Parkinsonism	1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -														
	Somnolence											3000		1	1	
	Status epilepticus									2						
	Tardive dyskinesia									1	1					
	Unresponsive to stimuli			4	4					1						
	SOC Subtotal			8	8					9	9			2	2	



Report Runtime: 2022-02-16 9:29 AM Health Product: See Search Criteria Age:

Health Product Role:

Seriousness:

All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Total Number of Reports: 35

> All ΑII

Gender:

MedDRA Version:

Foreign or Domestic: Domestic

					20	21		000000000000000000000000000000000000000		
			Octo	ober	Nove	mber	Dece	mber		10
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Dyskinesia		1	1					2	2
	Generalised tonic- clonic seizure				1	1			1	1
	Hypotonia								1	1
	Lethargy		1	1					1	1
	Mental impairment	7					1	1	2	2
Nervous system disorders	Myelopathy								1	1
	Parkinsonism		-1						2	2
	Somnolence						1	1	2	2
	Status epilepticus				1	1			1	1
	Tardive dyskinesia		1	1					2	2
	Unresponsive to stimuli				2	2			7	7
	SOC Subtotal		6	6	6	6	2	2	33	33



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Report Runtime: 2022-02-16 9:29 AM Total Number of Reports: 35
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

									2021							
		Febr	uary	Ma	rch	Ap	oril	Ma	ay	Ju	ne	Ju	ily	Aug	just	Septembe
soc	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Confusional state									1	1			1	1	
	Depression	::::- 4	4			22	2	{:1	1	4	4	1	2	1	1	2
sychiatric disorders	Drug abuse			1	1	1	in i	44			hi-t	1	1			
	Hallucination					Z				J		:	r		7	2
	Suicide attempt									1	1					
	SOC Subtotal	4	4	1	1	2	2	1	1	7	7	1	1	2	2	2
				I	I		1			1	1	T	1	T	T	T
	Atelectasis							52		31	1					
	Dyspnoea									1	1	1	1			
Respiratory, thoracic	Pulmonary embolism										1					
lisorders	Rales									1	1					
	Respiratory depression													1	1	
	Respiratory failure															
	SOC Subtotal									4	4	1	1	1	1	



Report Runtime:2022-02-16 9:29 AMTotal Number of Reports:35Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

					20	21				
			Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Confusional state		1	1	100000		1	1	4	4
	Depression	2	1	1	1	11		Z	16	16
Psychiatric disorders	Drug abuse								2	2
	Hallucination]	1	1			Z		2	2
	Suicide attempt								1	1
	SOC Subtotal	2	3	3	1	1	1	1	25	25
			1	I	1		1		T	I
	Atelectasis						5		1	1
	Dyspnoea								2	2
Respiratory, thoracic and mediastinal	Pulmonary embolism				<i></i>				1	1
disorders	Rales								1	1
	Respiratory depression						1		2	2
	Respiratory failure		1	1					1	1
	SOC Subtotal		1	1			1	1	8	8



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Report Runtime: Health Product: All See Search Criteria Age: Gender: ΑII Health Product Role:

All MedDRA Version: Seriousness:

2022-02-16 9:29 AM

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

								all the second	2021							
		Febr	uary	Ma	rch	Aį	oril	Ma	ay	Ju	ne	Ju	ily	Aug	just	September
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
Skin and subcutaneous	Stevens-Johnson syndrome															
tissue disorders	Toxic epidermal necrolysis															
SHIP TO SHIP THE SHIP	SOC Subtotal															
Social circumstances	Loss of personal independence in daily activities															
	SOC Subtotal							1	1							1
Vascular disorders	Deep vein thrombosis									1	1					
	SOC Subtotal									1	1					
	Grand Total	8	8	10	10	4	4	9	9	35	35	13	13	18	18	7

Total Number of Reports:

35



Report Runtime: 2022-02-16 9:29 AM Health Product: See Search Criteria

All

Total Number of Reports: 35

All Age: Gender: All

Health Product Role:

MedDRA Version:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

					20	21				
	Stevens-Johnson syndrome Toxic epidermal necrolysis SOC Subtotal Loss of personal independence in daily activities		Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Skin and subcutaneous					1				1	1
tissue disorders					1	1			1	1
	SOC Subtotal				2	2			2	2
Social circumstances	independence in daily		5						4	4
	SOC Subtotal	1	1	1	1	1			4	4
Vascular disorders	Deep vein thrombosis								1	1
	SOC Subtotal								1	1
	Grand Total	7	16	16	20	20	16	16	156	156



Report Runtime: 2022-02-16 9:29 AM
Health Product: See Search Criteria

All

Total Number of Reports: 35
Age: All

Health Product Role:

Gender:

Seriousness:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

ΑII

		20	21	Total All Reactions	
soc	PT	All Reactions	Outcome Fatal		Total Outcome Fatal
	Disseminated intravascular coagulation	1	1	1	1
Blood and lymphatic system disorders	Leukocytosis	1	1	1	1
	Thrombocytopenia	1	1	1	1
	SOC Subtotal	3	3	3	3
	Cardiac failure	1	1	1	1
Cardiac disorders	Mitral valve incompetence	1:: 1	121	1	1
	Myocarditis	1	1	1	1
	Ventricular arrhythmia	2	2	2	2
	SOC Subtotal	5	5	5	5
Eye disorders	Eye movement disorder	1	1	1	1
	SOC Subtotal	1	1	1	1
Gastrointestinal disorders	Vomiting		1	1	1
	SOC Subtotal	1	1	1	1

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Report Runtime: 2022-02-16 9:29 AM
Health Product: See Search Criteria

Total Number of Reports: 35
Age: All
Gender: All

Health Product Role:

Initial Date of Receipt:

Gender: MedDRA Version:

Seriousness: All

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		2021			
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Accidental death	4	4	4	4
	Chest pain	1	1	1	1
	Death	3	3	3	3
	Drug interaction	18	18	18	18
General disorders and administration site conditions	Food interaction	2	2	2	2
	Malaise	22	2	2	2
	Multiple-drug resistance	1	1	1	1
	Potentiating drug interaction	2	2	2	2
	Pyrexia	1	1	1	1
	Sudden unexplained death in epilepsy	1		1	4
	Unmasking of previously unidentified disease	2	2	2	2
	SOC Subtotal	37	37	37	37

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Report Runtime:2022-02-16 9:29 AMTotal Number of Reports:35Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Infections and	Endocarditis	1 1 1	1	1	1
infestations	Pneumonia	3	3	3	3
	SOC Subtotal	4	4	4	4

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Report Runtime: 2022-02-16 9:29 AM
Health Product: See Search Criteria

ΑII

Total Number of Reports: 35 Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

			21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Failure to suspend medication	2	2	2	2
	Incorrect route of product administration	1	1	1	1
	Intentional overdose			1	1
	Intentional product use issue	2	2	2	2
	Labelled drug-drug interaction issue	2	2	2	2
Injury, poisoning and procedural complications	Prescribed overdose	2	2	2	2
	Product dose omission issue			1	1
	Product use in unapproved indication	2	2	2	2
	Skin injury			1	1
	Toxicity to various agents	4	4	4	4
	Wrong patient received product	2	2	2	2
	SOC Subtotal	20	20	20	20



Report Runtime:2022-02-16 9:29 AMTotal Number of Reports:35Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		2021			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Ammonia increased	1	1	1	1
	Antidepressant drug level above therapeutic	2	2	2	2
	Antipsychotic drug level increased	1	1	1	1
Investigations	Blood creatine phosphokinase increased	1	1 1	1	1
	Electrocardiogram QT prolonged	2	2	2	2
	Haemoglobin decreased	13-11-12-13-13-13-13-13-13-13-13-13-13-13-13-13-	1 /-	1	1
	Neutrophil count increased	1	1	1	1
	Postmortem blood drug level	2	2	2	2
	White blood cell count increased	1	1	1	1
	SOC Subtotal	12	12	12	12
	Brain oedema		1 2-1/-	1	1
Nervous system disorders	Cerebral amyloid angiopathy	2	2	2	2
	Dementia Alzheimer's type	2	2	2	2
	Dizziness	6	6	6	6
	Dyskinesia	2	2	2	2

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Report Runtime: 2022-02-16 9:29 AM
Health Product: See Search Criteria

All

Total Number of Reports: 35 Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	2021		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Generalised tonic- clonic seizure	1	1	1	1
	Hypotonia		1 2 1 2 1	1	1
Nervous system	Lethargy	1	1	1	1
	Mental impairment	2	2	2	2
	Myelopathy	1	1	1	1
disorders	Parkinsonism	2	2	2	2
	Somnolence	2	2	2	2
	Status epilepticus	1	i 1	1	1
	Tardive dyskinesia	2	2	2	2
	Unresponsive to stimuli	7	7	7	7
	SOC Subtotal	33	33	33	33

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Report Runtime: 2022-02-16 9:29 AM Health Product: See Search Criteria

All Age: All

Health Product Role:

Gender:

All Seriousness:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

35

		2021			
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Confusional state	4	4	4	4
	Depression	16	16	16	16
Psychiatric disorders	Drug abuse	2	2	2	2
	Hallucination	2	2	2	2
	Suicide attempt	1	1	1	1
	SOC Subtotal	25	25	25	25

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Report Runtime: 2022-02-16 9:29 AM
Health Product: See Search Criteria

rch Criteria Age: Gender:

Seriousness: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

35

All

ΑII

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Atelectasis	1		1	1
	Dyspnoea	2	2	2	2
Respiratory, thoracic and	Pulmonary embolism			1	1
mediastinal disorders	Rales	4**	1	1	1
	Respiratory depression	2	2	2	2
	Respiratory failure	1	1	1	1
	SOC Subtotal	8	8	8	8
Skin and subcutaneous	Stevens-Johnson syndrome	i1	1	1	1
tissue disorders	Toxic epidermal necrolysis	1	1	1	1
	SOC Subtotal	2	2	2	2

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Report Runtime:2022-02-16 9:29 AMTotal Number of Reports:35Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Health Product Role: Gender:
Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		20	21		
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Social circumstances	Loss of personal independence in daily activities	4	4	4	4
	SOC Subtotal	4	4	4	4
Vascular disorders	Deep vein thrombosis	1	1	1	1
	SOC Subtotal	1	1	1	1
STATE OF THE STATE	Grand Total	156	156	156	156



Search Criteria

Report Runtime:	2022-02-16 - 9:59 AM 1.22 minutes
Range for Initial Date Received	2021-01-01 to 2021-12-31
AER No(s)	
Country of Occurence	Domestic
Case Serious?	All
Case Outcome	Fatal
Report Source	All
Patient Gender	All
Range for Age (years)	All
Reporter Type	All
Source Company Unit	All
Product Role	
Product Class	All
Product Description	All
DIN/NPN	
	dextroamphetamine-amphetamine DEXTROAMPHETAMINE [DEXAMFETAMINE] dextroamphetamine sulfate dextroamphetamine saccharate dextroamphetamine DEXTROAMPHETAMINE DEXTROAMPHETAMINE SACCHARATE DEXTROAMPHETAMINE SULFATE Dextroamphetamine dextroamphetamine amphetamine methylenedioxymethamphetamine METHAMPHETAMINE HYDROCHLORIDE AMPHETAMINE ASPARTATE MONOHYDRATE methamphetamine saccharate 2,5-dimethoxy-4-methylamphetamine AMPHETAMINE SALT COMBO

CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement. (10/2007).



Glossary/Abbreviations

Term	Definition		
Age		renambatecome as mad algem some has been some of the advers aramphatamoine caud fate ports where the age is unknown.	se
AR	Adverse Reaction	methylenedioxyamphetamine amphetamine aspartate	
Gender	Gender of the patient as it was provi reaction reports and gender specific	de อัฐโฟล์ Tophary ชาติ อีสโลย เลย เลย อัฐโฟล์ อัฐโฟล์ อัฐโฟล์ เลย อัฐโฟล์ อั	lverse 1.
Health Product	A health product includes drugs and prescription pharmaceuticals; biotec vaccines, serums, and blood derived	ाम्सामान्त्रीत्राक्ष्मिक्ष्यक्ष्मित्र्वेडः. Drugs include both prescription and r hpology products such as preducts: disintents and radiopartmacquirals.	non-
Active Health Product Role	The characterization of the role of th Ingredient(s) health product role re reporter. Cause and effect relations reporter suspected the health produ	eMeditix he headexbythed find Mourter of the adverse permitted the individual hears with the individual hears with the individual hears with the indicates that the indicates the same of the same of the indicates days the indicates days the indicates and the indicates of the ind	the that
HLT	High Level Term – see definition of I	Megraphetamine sulphate	
HLGT	High Level Group Term – see definit	Methylenedioxymethamphetamine iଞ୍ଜ୍ୟୁଦ୍ୟୁଲିକ୍ୟୁଡିନିedioxy-N-methylamphetamine	
Initial Date of Receipt		methamphetamine adverse reaction report was received by Health Canada's Can METHAMPHETAMINE	ada
MedDRA	of terms used to facilitate the regula	DEXMETHYLPHENIDATE HYDROCHLORIDE ti如母和阿姆克斯	tion
MedDRA Version	reflects the version in use at the time	d งองการสากๆแก่ง คากและแบบคุม ของระทาบากขอ MedDRA version displa อย่องเกาะเกาะเกาะเกาะเกาะเกาะเกาะเกาะเกาะเกาะ	yed
NEC	Not Elsewhere Classified – MedDRA	Dexmethylphenidate hydrochloride abbreviation METHYLPHENIDATE HYDROCHLORIDE	
NOS	Not Otherwise Specified – MedDRA	1V1 to 1 1 1 to 1 V1 V	
PT	Preferred Term – A MedDRA Prefer (single medical concept) for a sympt surgical or medical procedure, and r	LISDEXAMFETAMINE red Term is an adverse reaction term which is a distinct description of the control of the con	otor ion,
Seriousness	The seriousness of the adverse react that required in-patient hospitalizational formation, that results in persistent and the seriousness of the adverse react that requires the seriousness of the adverse react that required in-patient hospitalization and the seriousness of the adverse react that required in-patient hospitalization and the seriousness of the adverse react that required in-patient hospitalization and the seriousness of the seriousness	tlisclexentifetansideoditheśdlatering reasons: an adverse reac nLucedetalmetanienieting=supdateation, that causes con ntsusignificetardisability that all the threatening, that results in ntsusieticalminetalmine DIMESYLATE	genital
SOC Dosag	System Organ Class – A System Or broadest concept for data retrieval. e Form	glindexemenanige especially the hierarchy that provides the Each adverse reaction term is assigned one primary SOC. All	-
Route	of Administration	All	
ATC		All	





ATC Pattern	All
Reaction PTs	All

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-16 9:59 AMTotal Number of Reports:32Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: Al

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

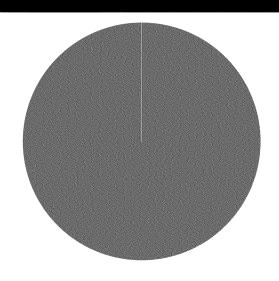
Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousn	ess
			Death	32
			Life Threatening	6
112	32	32	Hospitalization required	5
112	32	32	Disability	0
			Congenital Anomaly	0
			Other Medically	8

	Age Group	
ADULT	32	100.00%

	Patient Sex	
Female	10	31.25%
Male	22	68.75%



MedDRA Version:



M ADULT

The Definition for age groups has been taken from the International Conference on Harmonization (ICH) and have been defined as follows:

- Neonate greater than zero and up to 27 days, inclusively
- Infant greater than 27 days and less than 2 years
- Child greater or equal to 2 and less than 12 years
- Adolescent greater or equal to 12 and less than 19 years
- Adult greater or equal to 19 and less than 65 years
- Elderly greater or equal to 65 years

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

Health

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

MedDRA Version:

2022-02-16 9:59 AM Report Runtime: Total Number of Reports: 32 Health Product: See Search Criteria Αll Age: Health Product Role: Gender: All

Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

System Organ Class	Number of All Reactions*	Reactions* (% of total)	Number of Reactions* where outcome of AR report was fatal
Cardiac disorders	11	9.82%	5
Gastrointestinal disorders	2	1.79%	1
General disorders and administration site conditions	5	4.46%	1
Hepatobiliary disorders	2	1.79%	1
Infections and infestations	2	1.79%	2
Injury, poisoning and procedural complications	29	25.89%	5
Investigations	36	32.14%	8
Nervous system disorders	6	5.36%	4
Psychiatric disorders	14	12.50%	1
Renal and urinary disorders	2	1.79%	1
Respiratory, thoracic and mediastinal disorders	3	2.68%	2
Total Number of Reactions	112	100.00%	31

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-16 9:59 AM Total Number of Reports: 32
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

System Organ Class		Number of	
HLGT		Number of All Reactions*	Reactions* where outcome
HLT	PT	rveactions	of report was
Cardiac disorders			
Cardiac arrhythmias			
Ventricular arrhythmias and cardiac	Cardiac arrest	2	2
arrest	Cardio-respiratory arrest	5	5
Heart failures			
Heart failures NEC	Cardiogenic shock	1	1
Right ventricular failures	Cor pulmonale	1	1
Myocardial disorders			
Myocardial disorders NEC	Left ventricular dysfunction	2	2
		T	
	Cardiac disorders SOC Total	11	11
Gastrointestinal disorders			
Gastrointestinal vascular conditions			
Gastrointestinal vascular occlusion and infarction	Intestinal infarction	2	2
Gas	strointestinal disorders SOC Total	2	2

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:59 AM Total Number of Reports: 32 Αll Health Product: See Search Criteria Age: Health Product Role: All Gender: Seriousness: MedDRA Version: Foreign or Domestic: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Domestic General disorders and administration site conditions **Fatal outcomes** 5 Death and sudden death 5 Death 5 General disorders and administration site conditions SOC Total 5 Hepatobiliary disorders Hepatic and hepatobiliary disorders Hepatocellular damage and hepatitis 2 2 NEC Hepatic necrosis 2 **Hepatobiliary disorders SOC Total** 2 Infections and infestations Infections - pathogen unspecified 1 1 Pneumonia aspiration Lower respiratory tract and lung infections 1 1 Pneumonia necrotising Infections and infestations SOC Total 2 2

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-16 9:59 AM Total Number of Reports: 32 Αll Health Product: See Search Criteria Age: Health Product Role: All Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Injury, poisoning and procedural complications Exposures, chemical injuries and poisoning 3 3 Poisoning Poisoning and toxicity 19 19 Toxicity to various agents Injuries NEC Non-site specific injuries NEC 1 1 Fall Medication errors and other product use errors and issues Medication errors, product use errors and Product use in unapproved 1 1 issues NEC indication Overdoses and underdoses NEC 5 Overdoses NEC Overdose 5

Injury, poisoning and procedural complications SOC Total

Santé Canada

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-16 9:59 AM Total Number of Reports: 32
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All
Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-1	2-31 Foreign or Domest	tic: Dom	estic
nvestigations			
Toxicology and therapeutic drug monitoring			
	Amphetamines positive	10	10
	Antemortem blood drug level increased	1	1
	Blood ethanol	1	1
	Blood ethanol increased	3	3
Toxicology laboratory analyses	Opiates positive	9	9
	Postmortem blood drug level	5	5
	Postmortem blood drug level abnormal	3	3
	Postmortem blood drug level increased	4	4
	Investigations SOC Total	36	36
Nervous system disorders			
Encephalopathies			
Encephalopathies NEC	Hypoxic-ischaemic encephalopathy	2	2
Neurological disorders NEC			
Disturbances in consciousness NEC	Depressed level of consciousness	1	1
Seizures (incl subtypes)			
0	Seizure	1	1
Seizures and seizure disorders NEC	Status epilepticus	2	2
Ne	rvous system disorders SOC Total	6	6

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



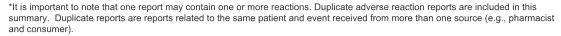
2022-02-16 9:59 AM

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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: Total Number of Reports: Αll Health Product: See Search Criteria Age: Health Product Role: All Gender: Seriousness: MedDRA Version: Foreign or Domestic: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Domestic **Psychiatric disorders** Psychiatric disorders NEC Substance related and addictive 14 disorders Drug abuse 14 **Psychiatric disorders SOC Total** 14 14 Renal and urinary disorders Renal disorders (excl nephropathies) 2 2 Renal vascular and ischaemic conditions Renal infarct 2 Renal and urinary disorders SOC Total 2 Respiratory, thoracic and mediastinal disorders Bronchial disorders (excl neoplasms) Chronic obstructive pulmonary Bronchospasm and obstruction 1 1 disease Lower respiratory tract disorders (excl obstruction and infection) Lower respiratory tract inflammatory and 2 2 immunologic conditions Pneumonitis Respiratory, thoracic and mediastinal disorders SOC Total 3 3





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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:59 AM Health Product: See Search Criteria

All

Total Number of Reports: Age: Gender:

Health Product Role:

Initial Date of Receipt:

MedDRA Version:

Seriousness:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

32

ΑII

All

							100		2021		3.5					
		Jani	uary	Febr	uary	Ma	rch	Ap	ril	M	ay	Ju	ne	Ju	ly	September
soc	PT	All Reactions	Outcome Fatal	All Reactions												
	Cardiac arrest							ZEZ.				33377		37.52		10757
	Cardiogenic shock							1	1							
Cardiac disorders	Cardio-respiratory arrest									7.15						
	Cor pulmonale							1	1							
	Left ventricular dysfunction									<u> </u>	5	Á				
	SOC Subtotal							2	2							
Gastrointestinal disorders	Intestinal infarction					1	1							1	1	
	SOC Subtotal					1	1							1	1	
General disorders and administration site conditions	Death			2	2			3								
	SOC Subtotal	1	1	2	2							1	1			1
Hepatobiliary disorders	Hepatic necrosis					1	1							1	1	
	SOC Subtotal					1	1							1	1	



Report Runtime: 2022-02-16 9:59 AM Total Number of Reports:
Health Product: See Search Criteria Age:
Health Product Role: Gender:

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

					20	21				
			Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Cardiac arrest		1	5215			515		2	2
	Cardiogenic shock								1	1
Cardiac disorders	Cardio-respiratory arrest		4	4	1				5	5
	Cor pulmonale								1	1
	Left ventricular dysfunction		(J1)	[] 1			1 ,	1	2	2
	SOC Subtotal		6	6	1	1	2	2	11	11
Gastrointestinal disorders	Intestinal infarction								2	2
	SOC Subtotal								2	2
General disorders and administration site conditions	Death	:							5	5
	SOC Subtotal	1		1. 1.1.1.1					5	5
Hepatobiliary disorders	Hepatic necrosis								2	2
	SOC Subtotal								2	2

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32

ΑII

All



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-16 9:59 AM Total Number of Reports: 32
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Initial Date of Red	ceipt: 2021-01-01 to	2021-12-3	I		Fore	eign or Dor	nestic:	Do	omestic							
							100		2021		3.7		71.00 27.72			Times of
		Jani	uary	Febr	uary	Mar	rch	Ap	ril	Ma	y	Ju	ne	Ju	ly	Septembe
soc	PT	All Reactions	Outcome Fatal	All Reactions												
nfections and	Pneumonia aspiration											1	16			
nfestations	Pneumonia necrotising											1	1			
	SOC Subtotal											2	2			
	Fall		36.2				2/1					533		365		365
	Overdose															
njury, poisoning and procedural complications	Poisoning															
	Product use in unapproved indication															
	Toxicity to various agents					4-3	4			2	2	3 -	3	2	2	
	SOC Subtotal					5	5	1	1	2	2	3	3	2	2	



Report Runtime: 2022-02-16 9:59 AM Total Number
Health Product: See Search Criteria Age:

Health Product Role:

Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31

SOC Subtotal

Total Number of Reports: 32

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

					20	21				
			Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Infections and	Pneumonia aspiration								1	1
infestations	Pneumonia necrotising								1	1
	SOC Subtotal								2	2
	1									
	Fall						397		1	1
	Overdose		4	4	1	1			5	5
Injury, poisoning and procedural complications	Poisoning				2	2			3	3
	Product use in unapproved indication				1	1			1	1
	Toxicity to various		1	Section .		Sant Sant			19	19

10

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Report Runtime: 2022-02-16 9:59 AM Total Number of Reports: 32
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

							17 200	- 100 miles	2021		- 2					
		Jani	uary	Febr	ruary	Ma	rch	Aŗ	oril	M	ay	Ju	ne	Ju	ily	September
soc	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Amphetamines positive					3	3			1	1	4	4			
	Antemortem blood drug level increased			200		1	1									
	Blood ethanol					1	1			<u> </u>	10.00			15.		***************************************
	Blood ethanol increased			j	<u> </u>		J	<u> </u>				2	2			Q
Investigations	Opiates positive					4	4		de la constante			3	3			
	Postmortem blood drug level					2	2			- 		1,				
	Postmortem blood drug level abnormal											2	2			
	Postmortem blood drug level increased					2	2	E-17	150	2915	235					
	SOC Subtotal					13	13	1	1	3	3	12	12			
	Depressed level of consciousness											1	1			
Nervous system	Hypoxic-ischaemic encephalopathy						د در									
disorders	Seizure									1	1					
	Status epilepticus															
	SOC Subtotal									1	1	1	1			



Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

Gender:

All

Report Runtime:2022-02-16 9:59 AMTotal Number of Reports:32Health Product:See Search CriteriaAge:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

					20	21		2 2 2		
			Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Amphetamines positive		2	2					10	10
	Antemortem blood drug level increased								1	1
	Blood ethanol								1	1
h	Blood ethanol increased		() 1	1					3	3
Investigations	Opiates positive		2	2					9	9
	Postmortem blood drug level			-1-					5	5
	Postmortem blood drug level abnormal		1	1					3	3
	Postmortem blood drug level increased		Parte						4	4
	SOC Subtotal		7	7					36	36
					T					
	Depressed level of consciousness								1	1
Nervous system	Hypoxic-ischaemic encephalopathy						Paris		2	2
disorders	Seizure								1	1
	Status epilepticus		13. 1 5.	1	5			[34]	2	2
	SOC Subtotal		2	2			2	2	6	6

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Report Runtime: 2022-02-16 9:59 AM Total Number of Reports:

Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

									2021							
		Janu	ıary	Febr	uary	Mai	ch	Ap	oril	M	ay	Ju	ne	Ju	ıly	September
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
Psychiatric disorders	Drug abuse											3	3			
	SOC Subtotal											3	3			
Renal and urinary lisorders	Renal infarct		5			1	1							:	1	
	SOC Subtotal					1	1							1	1	
Respiratory, thoracic	Chronic obstructive pulmonary disease							1	1							
nd mediastinal lisorders	Pneumonitis															
	SOC Subtotal							1	1							
	Grand Total	1	1	2	2	21	21	5	5	6	6	22	22	5	5	1

32



Report Runtime: 2022-02-16 9:59 AM
Health Product: See Search Criteria

All

Total Number of Reports: 32
Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

				015 to 1	20	21		1 1 1		
			Octo	ber	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Psychiatric disorders	Drug abuse		7	7	4	4			14	14
	SOC Subtotal		7	7	4	4			14	14
Renal and urinary disorders	Renal infarct								2	2
	SOC Subtotal								2	2
Respiratory, thoracic	Chronic obstructive pulmonary disease								1	1
and mediastinal disorders	Pneumonitis								2	2
	SOC Subtotal		1	1			1	1	3	3
	Grand Total	1	33	33	11	11	5	5	112	112

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Report Runtime: 2022-02-16 9:59 AM
Health Product: See Search Criteria

All

Total Number of Reports: 32 Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	21	07 gg	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Cardiac arrest	22	22	2	2
	Cardiogenic shock	1	1	1	1
Cardiac disorders	Cardio-respiratory arrest	5	5	5	5
	Cor pulmonale	1	1	1	1
	Left ventricular dysfunction	2	2	2	2
	SOC Subtotal	11	11	11	11
Gastrointestinal disorders	Intestinal infarction	2	2	2	2
	SOC Subtotal	2	2	2	2
General disorders and administration site conditions	Death	5	5	5	5
	SOC Subtotal	5	5	5	5
Hepatobiliary disorders	Hepatic necrosis	2	2	2	2
	SOC Subtotal	2	2	2	2
Infections and	Pneumonia aspiration	5.1.	1	1	1
infestations	Pneumonia necrotising	1	1	1	1
1000	SOC Subtotal	2	2	2	2

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A2021001920



Report Runtime: 2022-02-16 9:59 AM
Health Product: See Search Criteria

All

Age: All Gender: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

32

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Fall	1	1	1	1
	Overdose	5	5	5	5
Injury, poisoning and procedural complications	Poisoning	3	3	3	3
	Product use in unapproved indication	1	1	1	1
	Toxicity to various agents	19	19	19	19
	SOC Subtotal	29	29	29	29

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Report Runtime:2022-02-16 9:59 AMTotal Number of Reports:32Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Amphetamines positive	10	10	10	10
	Antemortem blood drug level increased	1 1	1	1	1
	Blood ethanol	1	1	1	1
l	Blood ethanol increased	3	3	3	3
Investigations	Opiates positive	9	9	9	9
	Postmortem blood drug level	5	5	5	5
	Postmortem blood drug level abnormal	3	3	3	3
	Postmortem blood drug level increased		4	4	4
200 Sept. 200 S	SOC Subtotal	36	36	36	36
	Depressed level of consciousness	1	1	1	1
Nervous system	Hypoxic-ischaemic encephalopathy	2	2	2	2
disorders	Seizure	1	1	1	1
	Status epilepticus	2	2	2	2
	SOC Subtotal	6	6	6	6
Psychiatric disorders	Drug abuse	14	14	14	14
	SOC Subtotal	14	14	14	14

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A2021001920



Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:59 AM
Health Product: See Search Criteria

See Search Criteria Age:
Gender:

Seriousness: All

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

32

ΑII

All

		20	21		
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Renal and urinary disorders	Renal infarct	2	2	2	2
	SOC Subtotal	2	2	2	2
Respiratory, thoracic and	Chronic obstructive pulmonary disease	1	1	1	1
mediastinal disorders	Pneumonitis	2	2	2	2
	SOC Subtotal	3	3	3	3
	Grand Total	112	112	112	112

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ATI-2021-001921

From January 1st, 2021 to December 31st, 2021, Health Canada's Canada Vigilance Program has received **1** fatal **domestic** adverse reaction (AR) reports with suspected **"Non-Stimulant ADHD"** products listed below.

"Strattera / Atomoxetine, Catapres / Clonidine, Kapvay, Intuniv / Guanfacine, Tenex, Qelbree / Viloxazine".

From January 1st, 2021 to December 31st, 2021, Health Canada's Canada Vigilance Program has received **62** fatal **domestic** adverse reaction (AR) reports with suspected **"Benzodiazepine"** products listed below.

"Alprazolam / Xanax, Chlordiazepoxide / Librium, Clorazepate / Tranxene, Diazepam / Valium, Halazepam / Paxipam, Lorzepam / Ativan, Oxazepam / Serax, Prazepam / Centrax, Quazepam / Doral, Clonazepam / Klonopin".

Please note the following caveats:

- It is often not possible to determine whether an adverse reaction reported to Health Canada is a result of using a specific health product. Other factors contributing to the reaction could be a person's health conditions or other health products they are using at the same time.
- Adverse reaction reports are suspected associations and reflect the opinion or observation of the individual reporter. The data do not reflect any Health Canada assessment of association between the health product and the reaction(s).
- Please consult the following <u>link</u> for additional caveats on the interpretation of suspected adverse reaction data collected by the Canada Vigilance program.

Page: 1 of/de 49 A2021001921



Search Criteria

Report Runtime:	2022-02-16 - 11:23 AM 2.15 minutes		
Range for Initial Date Received	2021-01-01 to 2021-12-31		
AER No(s)			
Country of Occurence	Domestic		
Case Serious?	All		
Case Outcome	Fatal		
Report Source	All		
Patient Gender	All		
Range for Age (years)	All		
Reporter Type	All		
Source Company Unit	All		
Product Role			
Product Class	All		
Product Description	All		
DIN/NPN			
	ALPRAZOLAM Alprazolam alprazolam ALPRAZOLAMUM chlordiazepoxide CHLORDIAZEPOXIDE HYDROCHLORIDE, CLIDINIU CHLORDIAZEPOXIDE? CLIDINIUM BROMIDE? DICY chlordiazepoxide hydrochloride CHLORDIAZEPOXIDE HYDROCHLORIDE CHLORDIAZEPOXIDE Chlordiazepoxide Hydrochloride Chlordiazepoxide CHLORDIAZEPOXIDE? CLIDINIUM CHLORDIAZEPOXIDE? CLIDINIUM CHLORDIAZEPOXIDE HYDROCHLORIDE? CLIDINIU clorazepate monopotassium clorazepate DIPOTASSIUM CLORAZEPATE		

CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement. (10/2007).



Glossary/Abbreviations

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Term	Definition		
Age		r செருக்கு செரு பிரு பிரு பிரு பிரு பிரு பிரு பிரு பி	e
AR	Adverse Reaction	CLORAZEPATE DIPOTASSIUM CLORAZEPATE DIPOTASSIQUE	
Gender	Gender of the patient as it was provi reaction reports and gender specific	deltAZี่โลกผู้อาการคลาย รอยายออกเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่องเรื่อง NORDIAZEPAM	verse 1.
Health Product	A health product includes drugs and prescription pharmaceuticals; biotectoraccines, serums, and blood derived	ന് ചുപ്പളി ഉണ്ടി th products. Drugs include both prescription and r hpറിറ്റ്ളെ ഉപ്പൂcts and biologically-derived products such as	ion-
Health Product Agting	reaction. The health product role re reporter. Cause and effect relations reported subsected the health produ	e Modia (Approvided by the original reporter of the adverse passage in the individual high passage in the individual high passage in the individual high passage in the indicates that characteristics. A 'concomitant' role indicates deligible in the passage in the indicates of the passage in the indicates of the passage in the indicates of the passage in the indicate in the indicate in the indicate in the passage in the indicate indicate in the indicate in the indicate indicate in the indic	that
HLT	High Level Term – see definition of I	MDIAZEPAM? DICYCLOVERINE	
HLGT	High Level Group Term – see definit	FLUDIAZEPAM ignarazepan	
Initial Date of Receipt		HALAZEPAM adverse reaction report was received by Health Canada's Can Lorazepam	ada
MedDRA	of terms used to facilitate the regular terms in a hierarchical structure when of 'high level term' (HLT). 'High level which are then grouped by 'system'	lorazepam 3-o-phenolic glucuronide (pk ana) ctwitiezephedDRA is an internationally recognized standardize tior การเการะบาง เการ์ เก	tion ading)
MedDRA Version	The MedDRA terminology is update reflects the version in use at the time	d De la kazemuarh , scheduled basis. The MedDRA version displa	iyed
NEC	Not Elsewhere Classified – MedDRA	A SYSTEMANIA OXAZEPAM	
NOS	Not Otherwise Specified - MedDRA	aDXAZERAM SUCCINATE	
PT	Preferred Term – A MedDRA Prefer (single medical concept) for a sympt surgical or medical procedure, and r	Oxazepam red Term is an adverse reaction term which is a distinct descrip or sign disease, diagnosis, therapeutic indication, investigati nedical, social, or family history characteristic. flutoprazepam	otor on,
Seriousness	The seriousness of the adverse read that required in-patient hospitalization	ះ មើករយៈម្យាជក់ ន based on the following reasons: an adverse read រក ្សេ Joy មានស្វារៈទែក ស៊ីរ៉ុង xisting hospitalization, that causes cong រោ ងសុទ្ធនៅស្រុ ងរា disability, that is life threatening, that results in	tion genital
soc	System Organ Class – A System Or	gsiPthรรคิศัตย highest level of the hierarchy that provides the Estภาสระคริศักย ESTONAZEPAMUM	.
		CLONAZEPAM	
Dosag	je Form	All	
Route	of Administration	АП	





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	, wi
ATC	All
ATC Pattern	All
Reaction PTs	All

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62 All Health Product: See Search Criteria Age: Health Product Role: Gender: All MedDRA Version:

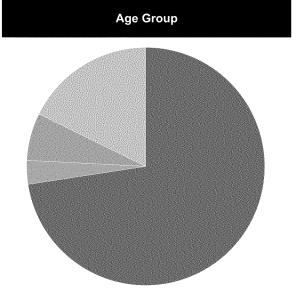
Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousn	ess
			Death	62
			Life Threatening	11
208	62	62	Hospitalization required	15
200	02	02	Disability	0
			Congenital Anomaly	0
			Other Medically	42

Age Group				
ADULT	45	72.58%		
CHILD	2	3.23%		
ELDERLY	4	6.45%		
UNKNOW N	11	17.74%		

	Patient Sex	
Female	22	35.48%
Male	40	64.52%



M ADULT CHILD M ELDERLY W UNKNOWN

The Definition for age groups has been taken from the International Conference on Harmonization (ICH) and have been defined as follows:

- Neonate greater than zero and up to 27 days, inclusively
- Infant greater than 27 days and less than 2 years
- Child greater or equal to 2 and less than 12 years
- Adolescent greater or equal to 12 and less than 19 years
- Adult greater or equal to 19 and less than 65 years
- Elderly greater or equal to 65 years

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).





Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62 Health Product: See Search Criteria All Age: Health Product Role: Gender: All

MedDRA Version: Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

System Organ Class	Number of All Reactions*	Reactions* (% of total)	Number of Reactions* where outcome of AR report was fatal
Blood and lymphatic system disorders	3	1.44%	3
Cardiac disorders	9	4.33%	5
Gastrointestinal disorders	4	1.92%	2
General disorders and administration site conditions	32	15.38%	9
Hepatobiliary disorders	4	1.92%	2
Immune system disorders	1	0.48%	1
Injury, poisoning and procedural complications	65	31.25%	20
Investigations	8	3.85%	7
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	2.40%	5
Nervous system disorders	29	13.94%	11
Pregnancy, puerperium and perinatal conditions	2	0.96%	1
Psychiatric disorders	35	16.83%	8
Renal and urinary disorders	2	0.96%	1
Respiratory, thoracic and mediastinal disorders	2	0.96%	2
Social circumstances	4	1.92%	1
Vascular disorders	3	1.44%	3
Total Number of Reactions	208	100.00%	81

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62 Health Product: See Search Criteria All Age: Health Product Role: Gender: All MedDRA Version:

Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

System Organ Class			Number of
HLGT		Number of All Reactions*	Reactions* where outcome
HLT	PT	And the second s	of report was fatal
Blood and lymphatic system disorde	ers		
Anaemias nonhaemolytic and marrow dep	ression		
Anaemias NEC	Anaemia	1	1
Platelet disorders			
Thrombocytopenias	Thrombocytopenia	1	1
		1	
White blood cell disorders			
Leukocytoses NEC	Leukocytosis	1	1
Blood and lym	nphatic system disorders SOC Total	3	3
Cardiac disorders			
Cardiac arrhythmias			
Rate and rhythm disorders NEC	Arrhythmia	1	1
Nate and mythin disorders NEO	Bradycardia	1	1
	Cardiac arrest	1	1
Ventricular arrhythmias and cardiac arrest	Cardio-respiratory arrest	5	5
anest	1		
anest	Pulseless electrical activity	1	1

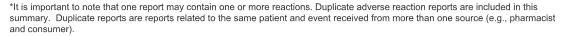
^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62 Health Product: See Search Criteria Age: Αll Health Product Role: ΑII Gender: MedDRA Version: Seriousness: All 2021-01-01 to 2021-12-31 Initial Date of Receipt: Foreign or Domestic: Domestic **Gastrointestinal disorders** Gastrointestinal vascular conditions Gastrointestinal vascular occlusion and 2 2 infarction Intestinal infarction Peritoneal and retroperitoneal conditions Peritoneal and retroperitoneal disorders 2 2 Ascites **Gastrointestinal disorders SOC Total** 4 4 General disorders and administration site conditions **Fatal outcomes** 3 3 Accidental death Death and sudden death 6 6 Death General system disorders NEC 2 2 Fatigue Asthenic conditions 1 1 Malaise 1 1 Disease progression General signs and symptoms NEC Multiple organ dysfunction 1 1 syndrome 1 1 Oedema NEC Oedema Therapeutic and nontherapeutic effects (excl toxicity) Interactions 16 16 Drug interaction 1 Withdrawal and rebound effects Drug withdrawal syndrome 1



General disorders and administration site conditions SOC Total



32

32

Pelvic fractures and dislocations

Health

Canada

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1

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62 All Health Product: See Search Criteria Age: Health Product Role: All Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Hepatobiliary disorders Hepatic and hepatobiliary disorders 2 2 Hepatic fibrosis and cirrhosis Hepatic cirrhosis Hepatocellular damage and hepatitis 2 2 Hepatic necrosis **Hepatobiliary disorders SOC Total** 4 4 Immune system disorders Allergic conditions Allergies to foods, food additives, drugs 1 and other chemicals Reaction to excipient Immune system disorders SOC Total 1 1 Injury, poisoning and procedural complications

-						
	Bone and joint injuries					
	Limb fractures and dislocations	Hip fracture	1	1		
	Limb fractures and dislocations	Wrist fracture	1	1		

Pelvic fracture

Exposures, chemical injuries and poisoning			
Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	1	1
	Poisoning	3	3
Poisoning and toxicity	Toxicity to various agents	20	20

Injuries NEC			
Abdominal and gastrointestinal injuries NEC	Abdominal injury	1	1
Cerebral injuries NEC	Brain herniation	2	2
Non-site specific injuries NEC	Fall	2	2

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



1

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: Health Product:

2022-02-16 11:23 AM

Total Number of Reports:

62 All

All

1

Health Product Role:

See Search Criteria

Gender:

Age:

Seriousness:

Non-site specific injuries NEC

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic:

Domestic

1

Medication errors and other product use error	s and issues		
Medication errors, product use errors and issues NEC	Product use in unapproved indication	3	3
	Failure to suspend medication	2	2
Product administration errors and issues	Incorrect route of product administration	1	1
	Wrong patient received product	2	2
Product monitoring errors and issues	Labelled drug-drug interaction issue	1	1

Road traffic accident

Off label uses and intentional product mis	suses/use issues		
Intentional product misuses	Intentional product misuse	1	1
Intentional product use issues	Intentional product use issue	2	2
Off label uses	Off label use	3	3

Overdoses and underdoses NEC			
O volume NEO	Overdose	15	15
Overdoses NEC	Prescribed overdose	2	2

Injury, poisoning and procedural complications SOC Total	65	65

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All
Seriousness: All MedDRA Version:

tial Date of Receipt: 2021-01-01 to 2021-	-12-31 Foreign or Domesti	ic: Dom	00110
vestigations			
Toxicology and therapeutic drug monitorin	g		
	Analgesic drug level	1	1
Therapeutic drug monitoring analyses	Antasthmatic drug level	1	1
	Benzodiazepine drug level therapeutic	1	1
	Blood ethanol increased	1	1
	Opiates positive	2	2
Toxicology laboratory analyses	Postmortem blood drug level abnormal	1	1
	Postmortem blood drug level increased	1	1
	Investigations SOC Total	8	8
eoplasms benign, malignant and u		8	8
Metastases		8	8
	nspecified (incl cysts and polyps)		
Metastases	Metastases to spine	1	1
Metastases Metastases to specified sites	Metastases to spine	1	1
Metastases Metastases to specified sites Nervous system neoplasms malignant and Central nervous system neoplasms	Metastases to liver Metastases to spine	1	1 1
Metastases Metastases to specified sites Nervous system neoplasms malignant and Central nervous system neoplasms malignant NEC Nervous system neoplasms malignant	Metastases to liver Metastases to spine unspecified NEC Malignant cranial nerve neoplasm	1 1	1 1

ms benign, malignant and unspecified (incl cysts and polyps) SOC Total



5

5

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

2022-02-16 11:23 AM

Report Runtime:

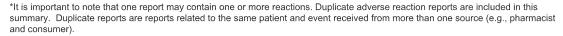
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62

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Total Number of Reports:

Health Product: See Search Criteria Age: Αll Health Product Role: All Gender: Seriousness: MedDRA Version: Foreign or Domestic: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Domestic Nervous system disorders Central nervous system vascular disorders 1 Haemorrhage intracranial 1 Central nervous system haemorrhages and cerebrovascular accidents 2 2 Ischaemic cerebral infarction Increased intracranial pressure and hydrocephalus 2 2 Increased intracranial pressure disorders Brain oedema Neurological disorders NEC 1 1 Lethargy 3 3 Disturbances in consciousness NEC Loss of consciousness 1 1 Somnolence 8 8 Dizziness Neurological signs and symptoms NEC 7 7 Unresponsive to stimuli Neuromuscular disorders 2 2 Muscle tone abnormal Serotonin syndrome Peripheral neuropathies 1 1 Mononeuropathies Nerve compression Structural brain disorders Structural brain disorders NEC 1 1 Brain injury





29

29

Nervous system disorders SOC Total

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

2022-02-16 11:23 AM Report Runtime: Total Number of Reports: 62 Health Product: See Search Criteria All Age: Health Product Role: Gender: All MedDRA Version: Seriousness: All

Seriousness: All	04.4. 0004.40.04	MedDRA Version:		
nitial Date of Receipt: 2021-01-	01 to 2021-12-31	Foreign or Domest	ic: Dom	estic
Pregnancy, puerperium and	perinatal condit	ions		
Abortions and stillbirth				
Stillbirth and foetal death	Fo	etal death	2	2
Pregnancy, pue	rperium and per	inatal conditions SOC Total	2	2
Psychiatric disorders				
Anxiety disorders and symptoms				
Anxiety symptoms	Ar	xiety	1	1
Depressed mood disorders and o	disturbances			
Depressive disorders	De	epression	16	16
Mood disorders and disturbance	s NEC			
Emotional and mood disturband	ces NEC Irr	itability	1	1
Psychiatric disorders NEC				
Mental disorders NEC	Me	ental disorder	2	2
Substance related and addictiv	e Dr	ug abuse	10	10
disorders	Dr	ug dependence	3	3
Sleep disorders and disturbance	s			
Disturbances in initiating and m sleep		somnia	1	1
Sleep disorders NEC	SI	eep disorder	1	1
	Psvo	chiatric disorders SOC Total	35	35

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist



2022-02-16 11:23 AM

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62

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: Total Number of Reports: All Health Product: See Search Criteria Age: Health Product Role: All Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Renal and urinary disorders Renal disorders (excl nephropathies) 2 2 Renal vascular and ischaemic conditions Renal infarct 2 Renal and urinary disorders SOC Total 2 Respiratory, thoracic and mediastinal disorders Lower respiratory tract disorders (excl obstruction and infection) Pulmonary oedemas 1 1 Pulmonary congestion Respiratory disorders NEC Respiratory failures (excl neonatal) 1 1 Respiratory failure Respiratory, thoracic and mediastinal disorders SOC Total 2 2 Social circumstances Lifestyle issues Loss of personal independence in Disability issues 4 4 daily activities Social circumstances SOC Total 4 4

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

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3

3

Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62 All Health Product: See Search Criteria Age: Health Product Role: All Gender: Seriousness: MedDRA Version: Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic Vascular disorders Decreased and nonspecific blood pressure disorders and shock 1 1 Hypotension Vascular hypotensive disorders 1 1 Orthostatic hypotension Vascular disorders NEC Site specific vascular disorders NEC 1 1 Pallor

Vascular disorders SOC Total

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).



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Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62
Health Product: See Search Criteria Age: All

Health Product Role: Gender:

Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Initial Date of Re	ceipt: 2021-01-01 t	0 2021-12-0	•		1 010	eign or Doi	nestic.	Di	omestic							
			2021													
		January		February		Mai	rch	Ар	April		May		June		ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Anaemia			1	1											
Blood and lymphatic system disorders	Leukocytosis			1	1											
	Thrombocytopenia			1	1											
	SOC Subtotal			3	3											
	Arrhythmia															
	Bradycardia	3								1	1 <u></u>	:			2	
Cardiac disorders	Cardiac arrest									1	1					
our dide disorders	Cardio-respiratory arrest															<u> </u>
	Pulseless electrical activity									1	1					
	SOC Subtotal									3	3					
Gastrointestinal	Ascites							[] 1	1					<u> </u>		<u> </u>
disorders	Intestinal infarction					1	1							1	1	
	SOC Subtotal					1	1	1	1					1	1	

MedDRA Version:

ΑII



Seriousness:

Canada Vigilance Summary of Product Adverse Reactions

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: Health Product: See Search Criteria

Health Product Role:

Initial Date of Receipt:

All

62

All Age: Gender: ΑII

MedDRA Version:

2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

			2021									
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Anaemia										1	1
Blood and lymphatic system disorders	Leukocytosis										1	1
	Thrombocytopenia							5			1	1
	SOC Subtotal										3	3
	Arrhythmia						1	1			1	1
	Bradycardia									,	1	1
Cardiac disorders	Cardiac arrest										1	1
Cardiac disorders	Cardio-respiratory arrest	1			4	4	1	(1) 1			5	5
	Pulseless electrical activity										1	16
	SOC Subtotal				4	4	2	2			9	9
Gastrointestinal	Ascites	1			<u> </u>		5 2	2 2	(1	2	2
disorders	Intestinal infarction										2	2
	SOC Subtotal								1	1	4	4



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Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

								-50	2021							
		Jan	uary	Febr	uary	Mai	rch	Aj	oril	Ma	ny	Ju	ne	Ju	ily	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions
	Accidental death	THE CONTROL OF THE CO								1	1					
	Death	1	1									1	1	2	2	
	Disease progression									1						
	Drug interaction			4	4			2	2	1	1	4	4			1
General disorders and administration site conditions	Drug withdrawal syndrome												12			
	Fatigue			1	1											
	Malaise															
	Multiple organ dysfunction syndrome															
	Oedema															
	SOC Subtotal	1	1	5	5			2	2	3	3	6	6	2	2	1



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Report Runtime: 2022-02-16 11:23 AM

2021-01-01 to 2021-12-31

2022-02-16 11:23 AM Total Number of Reports:
See Search Criteria Age:

Health Product Role:

Initial Date of Receipt:

Health Product:

Gender: MedDRA Version:

Seriousness: All

Foreign or Domestic: Domestic

62 All

ΑII

					2021								
			Septe	mber	Octo	ober	Nove	mber	Dece	mber			
SOC	РТ	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcom Fatal	
izanio del controlo	Accidental death						2	2			3	3	
	Death						1	1	1	1	6	6	
	Disease progression										1	1	
	Drug interaction	1	2	2	1	1	1	1			16	16	
General disorders and administration site conditions	Drug withdrawal syndrome										1	1	
	Fatigue						1	1			2	2	
	Malaise							1			1	1	
	Multiple organ dysfunction syndrome								1	1	1	1	
	Oedema						1				1	1	
	SOC Subtotal	1	2	2	1	1	7	7	2	2	32	32	



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Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

Initial Date of Rec	eipt: 2021-01-01 t					eign or Doi			omestic							
							100		2021							
		Jan	uary	Febr	ruary	Ma	rch	Aŗ	oril	Ma	ay	Ju	ine	Jı	ily	August
SOC	PT	All Reactions	Outcome Fatal	All Reaction												
	Hepatic cirrhosis							1	1				1			
lepatobiliary disorders	Hepatic necrosis	12		2	2	1:::::1::::::	11		2		7	2	2	21	1	
	SOC Subtotal					1	1	1	1					1	1	
nmune system isorders	Reaction to excipient					1	1									
	SOC Subtotal					1	1									
				<i>A</i>							2					
	Abdominal injury															
	Brain herniation							1	1							
	Exposure during pregnancy															
njury, poisoning and rocedural omplications	Failure to suspend medication									1	1					
	Fall															
	Hip fracture															
	Incorrect route of product administration															



Seriousness:

Canada Vigilance Summary of Product Adverse Reactions

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62 All Health Product: See Search Criteria Age:

Gender: Health Product Role: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

						20)21	70 00 000 00 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
			Septe	ember	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Hepatic cirrhosis								1	1	2	2
Hepatobiliary disorders	Hepatic necrosis				2	2	2	2::::::::::	2	2	2	2
	SOC Subtotal								1	1	4	4
Immune system disorders	Reaction to excipient										1	1
	SOC Subtotal										1	1
	Abdominal injury										1	1
	Brain herniation								1	1	2	2
	Exposure during pregnancy										1	1
Injury, poisoning and procedural complications	Failure to suspend medication						1	1			2	2
	Fall			1				1.1			2	2
	Hip fracture		1	1							1	1
	Incorrect route of product administration										1	1

ΑII



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Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

			35					2 m	2021							
		Jani	uary	Feb	ruary	Má	ırch	Aŗ	oril	М	ay	Ju	ne	Ju	ily	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Intentional product misuse															
	Intentional product use issue									1	3 1					
	Labelled drug-drug interaction issue															
	Off label use															
Injury, poisoning and procedural	Overdose									1	1					
complications	Pelvic fracture															
	Poisoning															
	Prescribed overdose										1					
	Product use in unapproved indication															
	Road traffic accident															



Health Product Role:

Canada Vigilance Summary of Product Adverse Reactions

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62 All Health Product: See Search Criteria Age: Gender: ΑII

All MedDRA Version: Seriousness:

				100 cm		20)21	40.40.40.40.				
			Septe	mber	Oct	ober	Nove	mber	Dece	mber	2000	
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Intentional product misuse						1	1			1	1
	Intentional product use issue			1							2	2
	Labelled drug-drug interaction issue						1	1			1	1
	Off label use										3	3
Injury, poisoning and procedural	Overdose				7	7	3	3	4	4	15	15
complications	Pelvic fracture						1	1			1	1
	Poisoning				1	1	2	2			3	3
	Prescribed overdose		1								2	2
	Product use in unapproved indication				2	2	1	1			3	3
	Road traffic accident						1	1			1	1



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Report Runtime:2022-02-16 11:23 AMTotal Number of Reports:62Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

initial Date of Rec	celpt: 2021-01-01 to	. 2021 12-0	•		. 010	eign or Do			omestic							
									2021						1 T	
		Jani	uary	Febr	uary	Ma	rch	Ap	oril	M:	ay	Ju	ne	Ju	ily	August
SOC	PT	All Reactions	Outcome Fatal	All Reaction												
Companies and Companies Assistance Delays Palassin Assistance and Companies and Compan	Toxicity to various agents					2	2			1	1	1	1	rd s	4	
njury, poìsoning and rocedural omplications	Wrist fracture															
	Wrong patient received product									1	1					
	SOC Subtotal			1	1	2	2	2	2	6	6	1	1	1	1	
	Analgesic drug level					1	App. 1							<u> </u>		
	Antasthmatic drug					1	1									
	Benzodiazepine drug level therapeutic											5.35				
nvestigations	Blood ethanol increased											1	1			
	Opiates positive					1						3715	1			
	Postmortem blood drug level abnormal					1	1									
	Postmortem blood drug level increased									1		1	1	<u> </u>		
	SOC Subtotal					4	4					4	4			



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Report Runtime: 2022-02-16 11:23 AM Total Number of Reports:

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

				15.527 2.70 (15.527 2.70 (15.527)		20)21					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Toxicity to various agents				7	7	5	5	3	3	20	20
Injury, poisoning and procedural complications	Wrist fracture			1							1	1
	Wrong patient received product						1	1			2	2
	SOC Subtotal		6	6	18	18	19	19	9	9	65	65
	Analgesic drug level				1:		1				1	1
	Antasthmatic drug										1	1
	Benzodiazepine drug level therapeutic										1	1
Investigations	Blood ethanol increased										1	1
	Opiates positive					درون دوخري روزورو					2	2
	Postmortem blood drug level abnormal										1	1
	Postmortem blood drug level increased										1	1
	SOC Subtotal										8	8



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Report Runtime:2022-02-16 11:23 AMTotal Number of Reports:62Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

								ele la	2021							
		Jani	uary	Febr	uary	Mai	ch	Ap	ril	Mi	ау	Ju	ne	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Malignant cranial nerve neoplasm			1	1											
	Metastases to liver															
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastases to spine			400	1											
	Neuroblastoma recurrent			1	1) }3 53(5)	
	Retro-orbital neoplasm	1950.0		1	1											
	SOC Subtotal			5	5											



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Report Runtime: 2022-02-16 11:23 AM Total Number of Reports:

Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

				10007		20)21					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Malignant cranial nerve neoplasm										1	1
	Metastases to liver										1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastases to spine										1	1
	Neuroblastoma recurrent										1	1
	Retro-orbital neoplasm										1	1
	SOC Subtotal										5	5

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Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62
Health Product: See Search Criteria Age: All
Health Product Role: Gender: All

Seriousness: All MedDRA Version:

								40	2021							
		Jan	uary	Febr	uary	Ma	rch	Aŗ	oril	М	ay	Ju	ne	Ju	ıly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
	Brain injury									1	1					
	Brain oedema							1	1							
	Dizziness					4	4									
	Haemorrhage intracranial															
	Ischaemic cerebral infarction							1	1							
Nervous system disorders	Lethargy															
	Loss of consciousness										1	1	35. 1			
	Nerve compression			1	1										:	
	Serotonin syndrome							1								
	Somnolence															
	Unresponsive to stimuli					4	.4		Artifica							
	SOC Subtotal			1	1	8	8	3	3	2	2	1	1			



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Report Runtime: 2022-02-16 11:23 AM
Health Product: See Search Criteria

Total Number of Reports: 62
Age: All

Health Product Role:

Gender: All

Seriousness: All

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

				1000		20)21	00 000 000 (1240)				
			Septe	mber	Oct	ober	Nove	mber	Dece	mber		
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Brain injury										1	1
	Brain oedema								1	1	2	2
	Dizziness		1				3	3			8	8
	Haemorrhage intracranial		1	1							1	1
	Ischaemic cerebral infarction								- 	1	2	2
Nervous system disorders	Lethargy				1	1					1	1
	Loss of consciousness								1.5	1 1	3	3
	Nerve compression										1	1
	Serotonin syndrome								1-	-1	2	2
	Somnolence						1	1			1	1
	Unresponsive to stimuli						2	2	[3/ 1	1	7	7
e e e e e e e e e e e e e e e e e e e	SOC Subtotal		2	2	1	1	6	6	5	5	29	29



Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports:
Health Product: See Search Criteria Age:

Health Product Role: Gender:
Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

									2021							
		Jani	ıary	Febr	uary	Mai	rch	Ap	oril	M	ay	Ju	ne	Ju	ıly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
Pregnancy, puerperium and perinatal conditions	Foetal death															
	SOC Subtotal															
							1		1				1			
	Anxiety		<i>2</i>	Z			2	Z	P		7		7		,	<i>2</i>
	Depression			4	4			2	2	1	1	4	4			1
	Drug abuse				13:		3;;	<u> </u>	33,		i:		1			
Psychiatric disorders	Drug dependence															
r sychiatric disorders	Insomnia													Z		Z
	Irritability											1	1			
	Mental disorder							1:1:	1,500		::			3:		
	Sleep disorder											1	1			
	SOC Subtotal			4	4			3	3	1	1	6	6			1
		I		T	I	1	T		1							1
Renal and urinary disorders	Renal infarct					1	1							1	2-1	
	SOC Subtotal					1	1							1	1	

62

All

ΑII



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Report Runtime: 2022-02-16 11:23 AM

ΑII

Total Number of Reports: 62
Age: All

Health Product Role:

Gender: All

Seriousness:

Health Product:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

See Search Criteria

Foreign or Domestic: Domestic

						20)21					
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Pregnancy, puerperium and perinatal conditions	Foetal death		2	2							2	2
	SOC Subtotal		2	2							2	2
							A		4			
	Anxiety				Z :			1			1	1
	Depression	1	2	2	1	1	1	1			16	16
	Drug abuse				5	5	4	4	11	35 1 5 5 5	10	10
	Drug dependence						1	1	2	2	3	3
Psychiatric disorders	Insomnia						- Jan 1	1			1	1
	Irritability										1	1
	Mental disorder				4.	4	11	1			2	2
	Sleep disorder										1	1
	SOC Subtotal	1	2	2	6	6	9	9	3	3	35	35
Renal and urinary disorders	Renal infarct	1, 11,1,		2		2				S	2	2
	SOC Subtotal	1,7,7									2	2



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Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: 62 Health Product: All See Search Criteria Age: Gender: ΑII Health Product Role:

All MedDRA Version: Seriousness:

							100	349	2021							
		Jani	uary	Febr	uary	Mai	rch	Ар	oril	Ma	ау	Ju	ine	Ju	ly	August
SOC	PT	All Reactions	Outcome Fatal	All Reactions												
Respiratory, thoracic and mediastinal	Pulmonary congestion															
disorders	Respiratory failure															
	SOC Subtotal															
Social circumstances	Loss of personal independence in daily activities									1	1					
	SOC Subtotal									1	1					
	Hypotension							E		1	Eg::1;::::	. i i j			E	
Vascular disorders	Orthostatic hypotension															
	Pallor			1	1			·		·						
	SOC Subtotal			1	1					1	1					
	Grand Total	1	1	20	20	18	18	12	12	17	17	18	18	6	6	2



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Report Runtime: 2022-02-16 11:23 AM

Health Product: See Search Criteria

Health Product Role:

All Seriousness:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

62 Total Number of Reports:

All Age: ΑII

Gender:

MedDRA Version:

Foreign or Domestic: Domestic

						20	121	100				
			Septe	mber	Octo	ober	Nove	mber	Dece	mber		
soc	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Respiratory, thoracic and mediastinal	Pulmonary congestion						1	1			1	1
and mediastinal disorders	Respiratory failure					<u> </u>					1	1
	SOC Subtotal				1	1	1	1			2	2
Social circumstances	Loss of personal independence in daily activities		1	1	1	1	1	1			4	4
	SOC Subtotal		1	1	1	1	1	1			4	4
	Hypotension			43			14		15		1	1
/ascular disorders	Orthostatic hypotension		1	1							1	1
	Pallor						· · · · · · · · · · · · · · · · · · ·		·		1	1
	SOC Subtotal		1	1							3	3
	Grand Total	2	16	16	32	32	45	45	21	21	208	208



Report Runtime: 2022-02-16 11:23 AM Health Product: See Search Criteria

All

Total Number of Reports: 62 Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	21	6400 mm	
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Anaemia	1	1	1	1
Blood and lymphatic system disorders	Leukocytosis	1	1	1	1
	Thrombocytopenia			1	1
	SOC Subtotal	3	3	3	3
	Arrhythmia	1	1	1	1
	Bradycardia	2:1 :		1	1
Cardiac disorders	Cardiac arrest	1	1	1	1
Cardiac disorders	Cardio-respiratory arrest	55	5	5	5
	Pulseless electrical activity	1	1	1	1
	SOC Subtotal	9	9	9	9
Gastrointestinal disorders	Ascites	2/2 5/2/	2	2	2
	Intestinal infarction	2	2	2	2
	SOC Subtotal	4	4	4	4

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Report Runtime: 2022-02-16 11:23 AM Health Product: See Search Criteria

Total Number of Reports: 62 All Age: ΑII

Health Product Role:

Gender:

All Seriousness:

MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		2021		6301 all	
soc	РТ	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Accidental death		3	3	3
	Death	6	6	6	6
	Disease progression	1		1	1
	Drug interaction	16	16	16	16
General disorders and administration site conditions	Drug withdrawal syndrome			1	1
	Fatigue	2	2	2	2
	Malaise	1		1	1
	Multiple organ dysfunction syndrome	1	1	1	1
	Oedema		1	1	1
	SOC Subtotal	32	32	32	32
Hepatobiliary disorders	Hepatic cirrhosis	2	2	2	2
	Hepatic necrosis	2	2	2	2
	SOC Subtotal	4	4	4	4

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Report Runtime: 2022-02-16 11:23 AM Health Product: See Search Criteria Age:

Health Product Role:

Seriousness:

All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Total Number of Reports: 62

All

Gender: ΑII

MedDRA Version:

Foreign or Domestic: Domestic

		20	21	2019	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Immune system disorders	Reaction to excipient	1	1	1	1
447	SOC Subtotal	1	1	1	1
	Abdominal injury	1	1 1 	1	1
	Brain herniation	2	2	2	2
	Exposure during pregnancy	1	1	1	1
	Failure to suspend medication	2	2	2	2
Injury, poisoning and procedural	Fall	2	2	2	2
complications	Hip fracture	1	1	1	1
	Incorrect route of product administration	1 1	1	1	1
	Intentional product misuse	1	1	1	1
	Intentional product use issue	2	2	2	2
	Labelled drug-drug interaction issue	1	1	1	1

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Report Runtime: 2022-02-16 11:23 AM

Health Product: See Search Criteria

See Search Criteria Age:
Gender:

Seriousness: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Initial Date of Receipt: 2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

62

All

ΑII

		20	21	C00	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Off label use	3	3	3	3
	Overdose	15	15	15	15
	Pelvic fracture			1	1
	Poisoning	3	3	3	3
Injury, poisoning	Prescribed overdose	2	2	2	2
and procedural complications	Product use in unapproved indication	3	3	3	3
	Road traffic accident	1		1	1
	Toxicity to various agents	20	20	20	20
	Wrist fracture			1	1
	Wrong patient received product	2	2	2	2
. (2011 - 2011 - 1201 - 120 2011 - 2011 - 1201 - 1201	SOC Subtotal	65	65	65	65

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Report Runtime: 2022-02-16 11:23 AM
Health Product: See Search Criteria

Age: All Gender: All

Health Product Role:

Initial Date of Receipt:

Gender: MedDRA Version:

Total Number of Reports:

Seriousness:

All Med 2021-01-01 to 2021-12-31 Fore

Foreign or Domestic: Domestic

62

2021 Total Total All Outcome soc PT Outcome Reactions Fatal Reactions Fatal Analgesic drug level -1 - 1 1 1 Antasthmatic drug 1 1 1 Benzodiazepine drug 1 -1 1 1 level therapeutic **Blood ethanol** Investigations 1 increased Opiates positive 2 2 2 2 Postmortem blood 1 1 drug level abnormal Postmortem blood ~1. 1 1 drug level increased SOC Subtotal 8 8 8

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Report Runtime: 2022-02-16 11:23 AM Health Product: See Search Criteria

All

Total Number of Reports: 62
Age: All

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

		20	21	6.115	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Malignant cranial nerve neoplasm	1	1	1	1
	Metastases to liver			1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastases to spine	1	1	1	1
	Neuroblastoma recurrent	100		1	1
	Retro-orbital neoplasm	1	1	1	1
200 200 200 200	SOC Subtotal	5	5	5	5

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Report Runtime:2022-02-16 11:23 AMTotal Number of Reports:62Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		20	21	0.00	
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Brain injury	1	1	1	1
	Brain oedema	2	2	2	2
	Dizziness	8	8	8	8
	Haemorrhage intracranial	1	1	1	1
Nervous system disorders	Ischaemic cerebral infarction	2	2	2	2
	Lethargy	1	1	1	1
	Loss of consciousness	3	3	3	3
	Nerve compression	1	1	1	1
	Serotonin syndrome	2	2	2	2
	Somnolence	1	1	1	1
	Unresponsive to stimuli	7	7	7	7
	SOC Subtotal	29	29	29	29
Pregnancy, puerperium and perinatal conditions	Foetal death	2	2	2	2
336	SOC Subtotal	2	2	2	2

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Seriousness:

Canada Vigilance Summary of Product Adverse Reactions

Gender:

MedDRA Version:

Report Runtime: 2022-02-16 11:23 AM Total Number of Reports: Health Product: See Search Criteria Age:

Health Product Role:

All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

		20	21	6-101 - 101 - 101	
soc	PT.	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Anxiety	1	1	1	1
	Depression	16	16	16	16
	Drug abuse	10	10	10	10
Psychiatric	Drug dependence	3	3	3	3
disorders	Insomnia	1	1 1 1 1 1 1	1	1
	Irritability	1	1	1	1
	Mental disorder	2	2	2	2
	Sleep disorder	1	1	1	1
	SOC Subtotal	35	35	35	35
Renal and urinary disorders	Renal infarct	2	2	2	2
	SOC Subtotal	2	2	2	2
Respiratory, thoracic and mediastinal disorders	Pulmonary congestion	1	1	1	1
	Respiratory failure		1	1	1
STREET SEEDS OF STREET	SOC Subtotal	2	2	2	2

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A2021001921

62 All

ΑII



Report Runtime: 2022-02-16 11:23 AM
Health Product: See Search Criteria

All

Age: All Gender: All

Health Product Role:

MedDRA Version:

Total Number of Reports:

Seriousness: Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

62

		20	21		
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Social circumstances	Loss of personal independence in daily activities	4	4	4	4
	SOC Subtotal	4	4	4	4
	Hypotension	{ 1 ;	7,000 1 ,000 00	1	1
Vascular disorders	Orthostatic hypotension	1	1	1	1
	Pallor	1	1	1	1
- 100 mm mm	SOC Subtotal	3	3	3	3
	Grand Total	208	208	208	208

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Search Criteria

Report Runtime:	2022-02-16 - 11:08 AM 0.8 minutes
Range for Initial Date Received	2021-01-01 to 2021-12-31
AER No(s)	
Country of Occurence	Domestic
Case Serious?	All
Case Outcome	Fatal
Report Source	All
Patient Gender	All
Range for Age (years)	All
Reporter Type	All
Source Company Unit	All
Product Role	
Product Class	All
Product Description	All
DIN/NPN	
Active Ingredient(s)	Atomoxetine ATOMOXETINE HYDROCHLORIDE ATOMOXETINE atomoxetine hydrochloride atomoxetine Atomoxetine Hydrochloride Atomoxetine Hydrochloride CLONIDINE CLONIDINE Clonidine Hydrochloride Clonidine CHLORHYDRATE D'APRACLONIDINE apraclonidine clonidine apraclonidine hydrochloride clonidine hydrochloride clonidine hydrochloride APRACLONIDINE HYDROCHLORIDE

CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement. (10/2007).



Glossary/Abbreviations

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Term	Definition
Age	Age of the patient when the adverse reaction reports and age specific search
AR	Adverse Reaction GUANFACINE HYDROCHLORIDE guanfacine hydrochloride
Gender	Gender of the patient as it was provided by the patient. The gender is unknown in some of the adverse reaction reports and gender specific sugarifies we not include reports where the gender is unknown.
Health Product	Guanfacine A health product includes drugs and natural realth products. Drugs include both prescription and non-prescription pharmaceuticals; biotechnology products and biologically-derived products such as vaccines, serums, and blood derived products; disinfectants; and radiopharmaceuticals.
Health Product ARcle	reaction. The health product role represents the suspicion, opinion or observation of the individual reporter. The health product role represents the suspicion, opinion or observation of the individual reporter. Suspect and effect relationships have not been established. A 'suspect' role indicates that the reporter suspected the health product caused the adverse reaction. A 'concomitant' role indicates that the health product was not suspected but the patient was taking the health product at the time of the adverse reaction. All
	High Level Term – see definition of MedDRA on PTs
HLGT	
Initial Date of Receipt	The date that the first version of the adverse reaction report was received by Health Canada's Canada Vigilance Program.
MedDRA	Medical Dictionary for Regulatory Activities – MedDRA is an internationally recognized standardized set of terms used to facilitate the regulation of medical products. MedDRA groups relate adverse reaction terms in a hierarchical structure whereby the 'preferred term' (PT) is grouped under the broader heading of 'high level term' (HLT). 'High level terms' are then grouped under 'high level group terms (HLGT) which are then grouped by 'system organ class' (SOC). The 'preferred term' is the most specific term on the Summary of Reported Adverse Reactions, while the 'system organ class' is the most general.
MedDRA Version	The MedDRA terminology is updated on a biannual, scheduled basis. The MedDRA version displayed reflects the version in use at the time of producing the summary.
NEC	Not Elsewhere Classified – MedDRA abbreviation
NOS	Not Otherwise Specified – MedDRA abbreviation
PT	Preferred Term – A MedDRA Preferred Term is an adverse reaction term which is a distinct descriptor (single medical concept) for a symptom, sign, disease, diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical, social, or family history characteristic.
Seriousness	The seriousness of the adverse reaction report is based on the following reasons: an adverse reaction that required in-patient hospitalization or a prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability, that is life threatening, that results in death or is considered a medically important condition.
soc	System Organ Class – A System Organ Class is the highest level of the hierarchy that provides the broadest concept for data retrieval. Each adverse reaction term is assigned one primary SOC.

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-16 11:08 AMTotal Number of Reports:1Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

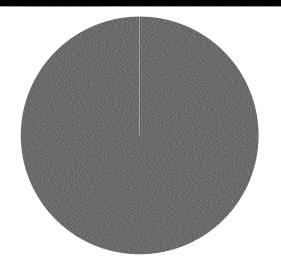
Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousne	ss
			Death	
			Life Threatening	
3 1	1	Hospitalization required		
•	•	•	Disability	
			Congenital Anomaly	
			Other Medically	

	Age Group	
ADULT	1	100.00%

Patient Sex						
Female	1	100.00%				



MedDRA Version:



M ADULT

The Definition for age groups has been taken from the International Conference on Harmonization (ICH) and have been defined as follows:

- Neonate greater than zero and up to 27 days, inclusively
- Infant greater than 27 days and less than 2 years
- Child greater or equal to 2 and less than 12 years
- Adolescent greater or equal to 12 and less than 19 years
- Adult greater or equal to 19 and less than 65 years
- Elderly greater or equal to 65 years

^{*}It is important to note that one report may contain one or more reactions. Duplicate adverse reaction reports are included in this summary. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer).

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Canada Vigilance Summary of Product Adverse Reactions Santé Canada

Report Runtime:2022-02-16 11:08 AMTotal Number of Reports:1Health Product:See Search CriteriaAge:AllHealth Product Role:Gender:All

Seriousness: All MedDRA Version:

System Organ Class	Number of All Reactions*	Reactions* (% of total)	Number of Reactions* where outcome of AR report was fatal
Injury, poisoning and procedural complications	2	66.67%	2
Psychiatric disorders	1	33.33%	1
Total Number of Reactions	3	100.00%	3

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Canada Vigilance Summary of Product Adverse Reactions

2022-02-16 11:08 AM Report Runtime: Total Number of Reports: 1 Health Product: See Search Criteria Αll Age: Health Product Role: Gender: All MedDRA Version:

Seriousness:

System Organ Class HLGT			Number of Reactions* where outcome	
		Number of All Reactions*		
HLT	[PT			
njury, poisoning and procedural c	omplications			
Exposures, chemical injuries and poison	ing			
Poisoning and toxicity	Toxicity to various agents	1	1	
		¬		
Overdoses and underdoses NEC				
Overdoses NEC	Overdose	1	1	
Injury, poisoning and	procedural complications SOC Total	2	2	
		٦		
Psychiatric disorders				
Psychiatric disorders NEC				
Substance related and addictive disorders	Drug dependence	1	1	
	Psychiatric disorders SOC Total	1	1	



MedDRA Version:

Report Runtime: 2022-02-16 11:08 AM Total Number of Reports:
Health Product: See Search Criteria Age:
Health Product Role: Gender:

Health Product Role: Seriousness: All

Initial Date of Receipt: 2021-01-01 to 2021-12-31 Foreign or Domestic: Domestic

2021 December Total All Total All Outcome PT soc Outcome Reactions Fatal Reactions Fatal 1 1 Injury, poisoning and Overdose procedural complications Toxicity to various 1 agents 2 **SOC Subtotal** 2 2 2

Psychiatric disorders	Drug dependence	1	1	1	1
	SOC Subtotal	1	1	1	1

Grand Total	3	3	3	3	
Grand Total	3	3	3	,	l

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1

Αll

ΑII



Report Runtime: 2022-02-16 11:08 AM
Health Product: See Search Criteria

All

Age: All

Total Number of Reports:

Health Product Role:

Gender: All

Seriousness:

MedDRA Version:

Initial Date of Receipt:

2021-01-01 to 2021-12-31

Foreign or Domestic: Domestic

1

		2021			
soc	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
and procedural complications	Overdose			1	1
	Toxicity to various agents	1	1	1	4
	SOC Subtotal	2	2	2	2
Psychiatric disorders	Drug dependence	1 1	1 1 1 1 1 1	1	1
	SOC Subtotal	1	1	1	1
	Grand Total	3	3	3	3

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