

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 [link](#) for additional caveats on the interpretation of suspected adverse reaction data collected by the Canada Vigilance program.
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Canada Vigilance

Summary of Product Adverse Reactions

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 Occurrence	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 Oxalate Citalopram 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

Term		Definition
	Age	Age of the patient when the adverse reaction occurred. The age is unknown in some of the adverse reaction reports and age specific searches will not include reports where the age is unknown.
	AR	Adverse Reaction
	Gender	Gender of the patient as it was provided by the reporter. The gender is unknown in some of the adverse reaction reports and gender specific searches will not include reports where the gender is unknown.
	Health Product	A health product includes drugs and natural health 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 Role	The characterization of the role of the product as provided by the original reporter of the adverse reaction. The health product role represents a suspicion, opinion or observation of the individual reporter. Cause 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.
	HLT	High Level Term – see definition of MedDRA
	HLGT	High Level Group Term – see definition of MedDRA
	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 periodically. 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.



Active Ingredient(s)	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
	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



	VENLAFAXINE
	venlafaxine hcl
	DESVENLAFAXINE SUCCINATE
	LEVOMILNACIPRAN HYDROCHLORIDE
	levomilnacipran
	levomilnacipran hydrochloride
	LEVOMILNACIPRAN
	Levomilnacipran
	Levomilnacipran hydrochloride
	amoxapine
	AMOXAPINE
	Amoxapine
	CLOMIPRAMINE
	clomipramine hydrochloride
	CLOMIPRAMINE HYDROCHLORIDE
	Clomipramine
	desmethyldomipramine
	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



	nortriptyline hydrochloride Nortriptyline hydrochloride NORTRIPTYLINE HYDROCHLORIDE NORTRIPTYLIN NORTRIPTYLINE Nortriptyline Nortriptyline Hydrochloride nortriptyline protriptyline hydrochloride protriptyline PROTRIPTYLINE HYDROCHLORIDE PROTRIPTYLINE ESMIRTAZAPINE mirtazapine MIRTAZAPINE Mirtazapine MIRTAZAPINE HYDROCHLORIDE bupropion bupropion hydrochloride BUPROPION HYDROBROMIDE Bupropion Hydrochloride BUPROPION BUPROPION HYDROCHLORIDE? NALTREXONE HY bupropion hydrobromide BUPROPION? ZONISAMIDE BUPROPION HYDROCHLORIDE Bupropion Bupropion hydrochloride Bupropion hydrobromide BUPROPION HCL trazodone Trazodone Trazodone Hydrochloride TRAZODONE HCL trazodone hydrochloride TRAZODONE HYDROCHLORIDE TRAZODONE
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

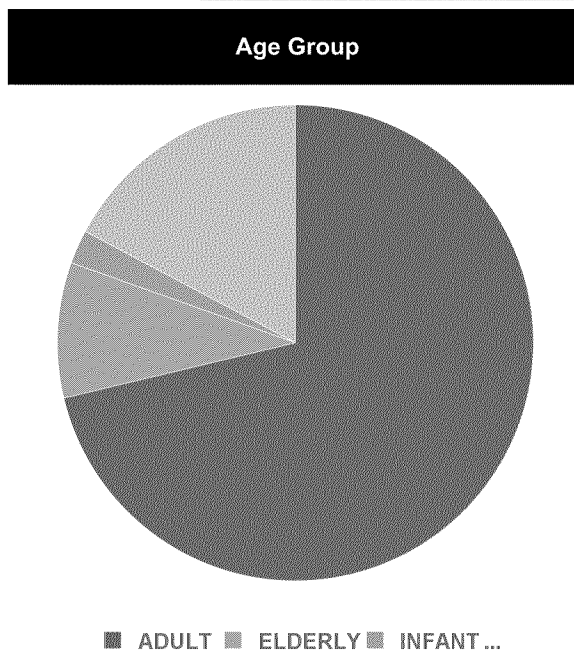
Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria
Health Product Role:
Seriousness: All
Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 87
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousness	
325	87	87	Death	87
			Life Threatening	7
			Hospitalization required	14
			Disability	1
			Congenital Anomaly	0
			Other Medically Important Condition	47

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

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



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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Total Number of Reports: 87
Age: All
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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

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System Organ Class	Number of All Reactions*	Number of Reactions* where outcome of report was fatal
HLGT		
HLT PT		

Cardiac disorders

Cardiac arrhythmias			
Cardiac conduction disorders	Bundle branch block right	1	1
Rate and rhythm disorders NEC	Arrhythmia	1	1
	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
Ischaemic coronary artery disorders	Acute coronary syndrome	1	1
	Myocardial infarction	1	1

Myocardial disorders

Myocardial disorders NEC	Left ventricular dysfunction	2	2
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Cardiac disorders SOC Total

23 23

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Report Runtime:	2022-02-15 3:11 PM	Total Number of Reports:	87
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Health Product Role:		Gender:	All
Seriousness:	All	MedDRA Version:	
Initial Date of Receipt:	2021-01-01 to 2021-12-31	Foreign or Domestic:	Domestic

Congenital, familial and genetic disorders

Neurological disorders congenital

Cerebral disorders congenital	Anencephaly	1	1
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Congenital, familial and genetic disorders SOC Total

1	1
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Gastrointestinal disorders

Gastrointestinal motility and defaecation conditions

Gastrointestinal atonic and hypomotility disorders NEC	Intestinal pseudo-obstruction	1	1
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Gastrointestinal signs and symptoms

Nausea and vomiting symptoms	Nausea	2	2
	Vomiting	1	1

Peritoneal and retroperitoneal conditions

Peritoneal and retroperitoneal disorders	Ascites	2	2
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Gastrointestinal disorders SOC Total

6	6
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General disorders and administration site conditions

Body temperature conditions

Body temperature altered	Temperature regulation disorder	1	1
Febrile disorders	Pyrexia	1	1

Fatal outcomes

Death and sudden death	Accidental death	5	5
	Death	10	10
	Death neonatal	1	1
	Hanging	1	1
	Sudden cardiac death	1	1

General system disorders NEC

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

Therapeutic and nontherapeutic effects (excl toxicity)

Interactions	Drug interaction	21	21
	Food interaction	2	2
	Potentiating drug interaction	2	2
	Tobacco interaction	1	1

General disorders and administration site conditions SOC Total

55 55

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Hepatobiliary disorders

Hepatic and hepatobiliary disorders

Hepatic fibrosis and cirrhosis	Hepatic cirrhosis	2	2
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Hepatobiliary disorders SOC Total

2 2

Infections and infestations

Bacterial infectious disorders

Bacterial infections NEC	Stenotrophomonas infection	1	1
Staphylococcal infections	Staphylococcal infection	1	1

Infections - pathogen unspecified

Lower respiratory tract and lung infections	Pneumonia	3	3
	Pneumonia aspiration	1	1
	Pneumonia necrotising	1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	Bacteraemia	1	1
	Sepsis	1	1

Infections and infestations SOC Total

9 9

Injury, poisoning and procedural complications

Bone and joint injuries

Pelvic fractures and dislocations	Pelvic fracture	1	1
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Exposures, chemical injuries and poisoning

Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	1	1
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Exposures associated with pregnancy, delivery and lactation	Maternal exposure during pregnancy	2	2
Poisoning and toxicity	Poisoning	3	3
	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
Non-site specific injuries NEC	Fall	3	3
	Road traffic accident	1	1
Site specific injuries NEC	Head injury	1	1

Medication errors and other product use errors and issues			
Medication errors, product use errors and issues NEC	Product use in unapproved indication	3	3
Product administration errors and issues	Accidental overdose	2	2
	Failure to suspend medication	2	2
	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 misuses/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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Overdoses and underdoses NEC			
Overdoses NEC	Intentional overdose	1	1
	Overdose	13	13
	Prescribed overdose	2	2
Injury, poisoning and procedural complications SOC Total		72	72

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Investigations

Cardiac and vascular investigations (excl enzyme tests)

ECG investigations	Electrocardiogram QT prolonged	3	3
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Investigations, imaging and histopathology procedures NEC

Imaging procedures NEC	X-ray	1	1
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Protein and chemistry analyses NEC

Chemistry analyses NEC	Serum serotonin increased	1	1
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Toxicology and therapeutic drug monitoring

Therapeutic drug monitoring analyses	Analgesic drug level above therapeutic	1	1
	Antidepressant drug level above therapeutic	3	3
	Benzodiazepine drug level therapeutic	1	1
Toxicology laboratory analyses	Alcohol test positive	2	2
	Amphetamines positive	1	1
	Blood ethanol increased	1	1
	Opiates positive	5	5
	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

Investigations SOC Total

29 29

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Metabolism and nutrition disorders

Acid-base disorders

Metabolic acidoses (excl diabetic acidoses)	Metabolic acidosis	1	1
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Appetite and general nutritional disorders

Appetite disorders	Decreased appetite	2	2
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Metabolism and nutrition disorders SOC Total

3 3

Musculoskeletal and connective tissue disorders

Musculoskeletal and connective tissue disorders NEC

Musculoskeletal and connective tissue pain and discomfort	Back pain	1	1
	Pain in extremity	1	1

Musculoskeletal and connective tissue disorders SOC Total

2 2

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Hepatobiliary neoplasms malignant and unspecified

Hepatic neoplasms malignant	Hepatic cancer	2	2
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Neoplasms benign, malignant and unspecified (incl cysts and polyps) SOC Total

2 2

Nervous system disorders

Central nervous system vascular disorders

Central nervous system haemorrhages and cerebrovascular accidents	Haemorrhage intracranial	1	1
	Ischaemic cerebral infarction	2	2

Encephalopathies

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Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Encephalopathies NEC	Hypoxic-ischaemic encephalopathy	2	2
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Headaches			
Headaches NEC	Headache	1	1

Increased intracranial pressure and hydrocephalus			
Increased intracranial pressure disorders	Brain oedema	2	2

Mental impairment disorders			
Mental impairment (excl dementia and memory loss)	Mental impairment	2	2

Neurological disorders NEC			
Coma states	Coma	1	1
Disturbances in consciousness NEC	Depressed level of consciousness	1	1
	Loss of consciousness	3	3
	Somnolence	4	4
Neurological signs and symptoms NEC	Dizziness	7	7
	Unresponsive to stimuli	7	7
Paraesthesias and dysaesthesias	Burning sensation	1	1
Speech and language abnormalities	Speech disorder	1	1

Neuromuscular disorders			
Muscle tone abnormal	Serotonin syndrome	2	2

Seizures (incl subtypes)			
Seizures and seizure disorders NEC	Status epilepticus	2	2

Structural brain disorders			
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Structural brain disorders NEC	Brain injury	1	1
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Nervous system disorders SOC Total		40	40
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Pregnancy, puerperium and perinatal conditions

Abortions and stillbirth			
Stillbirth and foetal death	Foetal death	2	2

Pregnancy, puerperium and perinatal conditions SOC Total		2	2
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Psychiatric disorders

Anxiety disorders and symptoms			
Anxiety symptoms	Anxiety	1	1

Deliria (incl confusion)			
Confusion and disorientation	Confusional state	4	4

Depressed mood disorders and disturbances			
Depressive disorders	Depression	16	16

Psychiatric and behavioural symptoms NEC			
Psychiatric symptoms NEC	Psychiatric decompensation	1	1

Psychiatric disorders NEC			
Mental disorders NEC	Mental disorder	2	2
Substance related and addictive disorders	Drug abuse	13	13
	Drug dependence	3	3

Sleep disorders and disturbances

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Disturbances in initiating and maintaining sleep	Insomnia	1	1
Sleep disorders NEC	Sleep disorder	1	1

Suicidal and self-injurious behaviours NEC			
Suicidal and self-injurious behaviour	Completed suicide	5	5
	Suicidal ideation	1	1
	Suicide attempt	1	1

Psychiatric disorders SOC Total	49	49
--	-----------	-----------

Reproductive system and breast disorders			
Prostatic disorders (excl infections and inflammations)			
Prostatic neoplasms and hypertrophy	Benign prostatic hyperplasia	2	2

Reproductive system and breast disorders SOC Total	2	2
---	----------	----------

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Canada Vigilance Summary of Product Adverse Reactions

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Foreign or Domestic: Domestic

Respiratory, thoracic and mediastinal disorders

Bronchial disorders (excl neoplasms)

Bronchospasm and obstruction	Asthma	2	2
	Wheezing	1	1

Lower respiratory tract disorders (excl obstruction and infection)

Lower respiratory tract inflammatory and immunologic conditions	Pneumonitis	2	2
Pulmonary oedemas	Pulmonary congestion	2	2

Pulmonary vascular disorders

Pulmonary thrombotic and embolic conditions	Pulmonary embolism	2	2
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Respiratory disorders NEC

Breathing abnormalities	Respiratory depression	2	2
Conditions associated with abnormal gas exchange	Asphyxia	2	2
	Hypoxia	1	1

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	Angioedema	1	1
-------------	------------	---	---

Skin and subcutaneous tissue disorders SOC Total

1 1

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Social circumstances

Lifestyle issues

Disability issues	Loss of personal independence in daily activities	4	4
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Social circumstances SOC Total

4 4

Surgical and medical procedures

Gastrointestinal therapeutic procedures

Abdominal therapeutic procedures NEC	Laparotomy	1	1
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Therapeutic procedures and supportive care NEC

Therapeutic procedures NEC	Therapy change	2	2
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Surgical and medical procedures SOC Total

3 3

Vascular disorders

Decreased and nonspecific blood pressure disorders and shock

Circulatory collapse and shock	Shock	1	1
Vascular hypotensive disorders	Hypotension	2	2

Embolism and thrombosis

Peripheral embolism and thrombosis	Deep vein thrombosis	1	1
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Vascular disorders NEC

Site specific vascular disorders NEC	Pallor	1	1
--------------------------------------	--------	---	---

Vascular disorders SOC Total

5 5

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		2021														
		January		February		March		April		May		June		July		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
Cardiac disorders	Acute coronary syndrome	1	1													
	Arrhythmia															
	Arteriosclerosis coronary artery	1	1	1	1											
	Bradycardia									1	1					
	Bundle branch block right					1	1									
	Cardiac arrest					1	1			1	1					
	Cardio-respiratory arrest															
	Left ventricular dysfunction															
	Myocardial infarction											1	1			
	Pulseless electrical activity									1	1					
	Tachycardia					1	1									
	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



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 Gender: All
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		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
Cardiac disorders	Acute coronary syndrome										1	1
	Arrhythmia						1	1			1	1
	Arteriosclerosis coronary artery		1	1							3	3
	Bradycardia										1	1
	Bundle branch block right										1	1
	Cardiac arrest				1	1			1	1	4	4
	Cardio-respiratory arrest				4	4	1	1			5	5
	Left ventricular dysfunction				1	1			1	1	2	2
	Myocardial infarction										1	1
	Pulseless electrical activity										1	1
	Tachycardia										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	1									1	1
	SOC Subtotal	1									1	1



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

		2021														
		January		February		March		April		May		June		July		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
Gastrointestinal disorders	Ascites							1	1							
	Intestinal pseudo-obstruction					1	1									
	Nausea															
	Vomiting															
	SOC Subtotal					1	1	1	1							

General disorders and administration site conditions	Accidental death									1	1					1
	Asthenia					1	1									
	Death	1	1	1	1	2	2							2	2	1
	Death neonatal															
	Drug interaction			5	5			2	2	2	2	4	4			2
	Fatigue					1	1									
	Food interaction															1



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			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
Gastrointestinal disorders	Ascites								1	1	2	2
	Intestinal pseudo-obstruction										1	1
	Nausea		1	1					1	1	2	2
	Vomiting								1	1	1	1
	SOC Subtotal		1	1					3	3	6	6

General disorders and administration site conditions	Accidental death	1					2	2	1	1	5	5
	Asthenia										1	1
	Death	1					1	1	2	2	10	10
	Death neonatal		1	1							1	1
	Drug interaction	2	2	2	1	1	1	1	2	2	21	21
	Fatigue						1	1			2	2
	Food interaction	1							1	1	2	2



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		2021														
		January		February		March		April		May		June		July		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
General disorders and administration site conditions	Hanging					1	1									
	Malaise					1	1									1
	Multiple organ dysfunction syndrome															
	Oedema															
	Potentiating drug interaction															1
	Pyrexia					1	1									
	Sudden cardiac death															
	Temperature regulation disorder			1	1											
	Tobacco interaction					1	1									
	SOC Subtotal	1	1	7	7	8	8	2	2	3	3	4	4	2	2	7



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 Gender: All
 MedDRA Version:
 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
General disorders and administration site conditions	Hanging										1	1
	Malaise	1					1	1	1	1	4	4
	Multiple organ dysfunction syndrome								1	1	1	1
	Oedema						1	1			1	1
	Potentiating drug interaction	1							1	1	2	2
	Pyrexia										1	1
	Sudden cardiac death								1	1	1	1
	Temperature regulation disorder										1	1
	Tobacco interaction										1	1
SOC Subtotal		7	3	3	1	1	7	7	10	10	55	55



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		January		February		March		April		May		June		July		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
Hepatobiliary disorders	Hepatic cirrhosis							1	1							
	SOC Subtotal							1	1							

Infections and infestations	Bacteraemia					1	1									
	Pneumonia					1	1									1
	Pneumonia aspiration											1	1			
	Pneumonia necrotising											1	1			
	Sepsis					1	1									
	Staphylococcal infection					1	1									
	Stenotrophomonas infection					1	1									
	SOC Subtotal					5	5					2	2			1

Injury, poisoning and procedural complications	Abdominal injury															
	Accidental overdose											1	1			
	Brain herniation							1	1							



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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
Hepatobiliary disorders	Hepatic cirrhosis								1	1	2	2
	SOC Subtotal								1	1	2	2

Infections and infestations	Bacteraemia										1	1
	Pneumonia	1							1	1	3	3
	Pneumonia aspiration										1	1
	Pneumonia necrotising										1	1
	Sepsis										1	1
	Staphylococcal infection										1	1
	Stenotrophomonas infection										1	1
	SOC Subtotal	1							1	1	9	9

Injury, poisoning and procedural complications	Abdominal injury						1	1			1	1
	Accidental overdose				1	1					2	2
	Brain herniation		1	1					1	1	3	3



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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
Injury, poisoning and procedural complications	Exposure during pregnancy															
	Failure to suspend medication									1	1					
	Fall					1	1									
	Head injury															
	Heat stroke			1	1											
	Incorrect route of product administration															
	Intentional overdose			1	1											
	Intentional product misuse															
	Intentional product use issue									1	1					
	Labelled drug-drug interaction issue															1



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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
Injury, poisoning and procedural complications	Exposure during pregnancy		1	1							1	1
	Failure to suspend medication						1	1			2	2
	Fall		1	1			1	1			3	3
	Head injury		1	1							1	1
	Heat stroke										1	1
	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



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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
Injury, poisoning and procedural complications	Maternal exposure during pregnancy															1
	Off label use	1	1					1	1							
	Overdose			1	1					1	1					
	Pelvic fracture															
	Poisoning															
	Prescribed overdose									1	1					
	Product use in unapproved indication	1	1													
	Road traffic accident															
	Toxicity to various agents	1	1	1	1	2	2			1	1	3	3	1	1	
	Wrong patient received product									1	1					
	SOC Subtotal	3	3	4	4	3	3	2	2	6	6	4	4	1	1	2



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		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
Injury, poisoning and procedural complications	Maternal exposure during pregnancy	1	1	1							2	2
	Off label use								1	1	3	3
	Overdose		1	1	5	5	1	1	4	4	13	13
	Pelvic fracture						1	1			1	1
	Poisoning				1	1	2	2			3	3
	Prescribed overdose		1	1							2	2
	Product use in unapproved indication				1	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



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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
Investigations	Alcohol test positive			1	1							1	1			
	Amphetamines positive											1	1			
	Analgesic drug level above therapeutic															
	Antidepressant drug level above therapeutic															1
	Benzodiazepine drug level therapeutic											1	1			
	Blood ethanol increased											1	1			
	Electrocardiogram QT prolonged															1
	Opiates positive			1	1							3	3			
	Postmortem blood drug level															1
	Postmortem blood drug level abnormal															
	Postmortem blood drug level increased					1	1					2	2			
	Serum serotonin increased									1	1					
	Toxicologic test abnormal			1	1							1	1			
	X-ray					1	1									
	SOC Subtotal			3	3	2	2			1	1	10	10			3



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		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
Investigations	Alcohol test positive										2	2
	Amphetamines positive										1	1
	Analgesic drug level above therapeutic								1	1	1	1
	Antidepressant drug level above therapeutic	1							2	2	3	3
	Benzodiazepine drug level therapeutic										1	1
	Blood ethanol increased										1	1
	Electrocardiogram QT prolonged	1							2	2	3	3
	Opiates positive								1	1	5	5
	Postmortem blood drug level	1							1	1	2	2
	Postmortem blood drug level abnormal		1	1	1	1					2	2
	Postmortem blood drug level increased										3	3
	Serum serotonin increased										1	1
	Toxicologic test abnormal								1	1	3	3
	X-ray										1	1
SOC Subtotal		3	1	1	1	1			8	8	29	29



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Health Product Role:

Seriousness: All

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Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

		2021														
		January		February		March		April		May		June		July		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
Metabolism and nutrition disorders	Decreased appetite					1	1									
	Metabolic acidosis			1	1											
	SOC Subtotal			1	1	1	1									
Musculoskeletal and connective tissue disorders	Back pain															
	Pain in extremity															
	SOC Subtotal															
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hepatic cancer					1	1							1	1	
	SOC Subtotal					1	1							1	1	
Nervous system disorders	Brain injury									1	1					
	Brain oedema							1	1							
	Burning sensation															
	Coma															



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		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
Metabolism and nutrition disorders	Decreased appetite								1	1	2	2
	Metabolic acidosis										1	1
	SOC Subtotal								1	1	3	3
Musculoskeletal and connective tissue disorders	Back pain		1	1							1	1
	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										2	2
Nervous system disorders	Brain injury										1	1
	Brain oedema								1	1	2	2
	Burning sensation				1	1					1	1
	Coma		1	1							1	1



Health
Canada

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Canada

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM
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: 87
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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

		2021														
		January		February		March		April		May		June		July		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
Nervous system disorders	Depressed level of consciousness											1	1			
	Dizziness					4	4									
	Haemorrhage intracranial															
	Headache															
	Hypoxic-ischaemic encephalopathy															
	Ischaemic cerebral infarction							1	1							
	Loss of consciousness									1	1	1	1			
	Mental impairment															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



Health
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Canada

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM
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: 87
Age: All
Gender: All
MedDRA Version:
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
Nervous system disorders	Depressed level of consciousness										1	1
	Dizziness						3	3			7	7
	Haemorrhage intracranial		1	1							1	1
	Headache		1	1							1	1
	Hypoxic-ischaemic encephalopathy				1	1			1	1	2	2
	Ischaemic cerebral infarction								1	1	2	2
	Loss of consciousness								1	1	3	3
	Mental impairment	1							1	1	2	2
	Serotonin syndrome								1	1	2	2
	Somnolence	1					1	1	1	1	4	4
	Speech disorder										1	1
	Status epilepticus				1	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



Health
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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria
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		2021														
		January		February		March		April		May		June		July		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															

Psychiatric disorders	Anxiety															
	Completed suicide			2	2	1	1									
	Confusional state			1	1											1
	Depression			4	4			2	2	1	1	4	4			1
	Drug abuse			1	1	1	1					1	1	1	1	
	Drug dependence															
	Insomnia															
	Mental disorder							1	1							
	Psychiatric decompensation									1	1					
	Sleep disorder															
	Suicidal ideation															
	Suicide attempt															
	SOC Subtotal			8	8	2	2	3	3	2	2	5	5	1	1	2

Reproductive system and breast disorders	Benign prostatic hyperplasia					1	1							1	1	
	SOC Subtotal					1	1							1	1	



Health
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Canada

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM
 Health Product: See Search Criteria
 Health Product Role:
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 Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 87
 Age: All
 Gender: All
 MedDRA Version:
 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
Pregnancy, puerperium and perinatal conditions	Foetal death		2	2							2	2
	SOC Subtotal		2	2							2	2

Psychiatric disorders	Anxiety						1	1			1	1
	Completed suicide				1	1	1	1			5	5
	Confusional state	1	1	1					1	1	4	4
	Depression	1	2	2	1	1	1	1			16	16
	Drug abuse				5	5	4	4			13	13
	Drug dependence						1	1	2	2	3	3
	Insomnia						1	1			1	1
	Mental disorder						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
	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



Health
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Canada

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria
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Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 87
Age: All
Gender: All
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		2021														
		January		February		March		April		May		June		July		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
Respiratory, thoracic and mediastinal disorders	Asphyxia			1	1											
	Asthma					1	1							1	1	
	Hypoxia					1	1									
	Oropharyngeal pain															
	Pneumonitis															
	Pulmonary congestion															
	Pulmonary embolism					1	1			1	1					
	Respiratory depression															1
	Wheezing					1	1									
	SOC Subtotal			1	1	4	4			1	1			1	1	1



Health
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Canada

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM
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		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
Respiratory, thoracic and mediastinal disorders	Asphyxia		1	1							2	2
	Asthma										2	2
	Hypoxia										1	1
	Oropharyngeal pain								1	1	1	1
	Pneumonitis				1	1			1	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



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Santé
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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM
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: 87
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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		2021														
		January		February		March		April		May		June		July		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 tissue disorders	Angioedema					1	1									
	SOC Subtotal					1	1									
Social circumstances	Loss of personal independence in daily activities									1	1					
	SOC Subtotal									1	1					
Surgical and medical procedures	Laparotomy					1	1									
	Therapy change									1	1					
	SOC Subtotal					1	1			1	1					
Vascular disorders	Deep vein thrombosis									1	1					
	Hypotension					1	1			1	1					
	Pallor					1	1									
	Shock			1	1											
	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



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Canada Vigilance Summary of Product Adverse Reactions

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

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: 87

Age: All

Gender: All

MedDRA Version:

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
Skin and subcutaneous tissue disorders	Angioedema										1	1
	SOC Subtotal										1	1
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
Surgical and medical procedures	Laparotomy										1	1
	Therapy change				1	1					2	2
	SOC Subtotal				1	1					3	3
Vascular disorders	Deep vein thrombosis										1	1
	Hypotension										2	2
	Pallor										1	1
	Shock										1	1
	SOC Subtotal										5	5
Grand Total		20	25	25	38	38	42	42	54	54	325	325



Canada Vigilance Summary of Product Adverse Reactions

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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: 87

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

		2021			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Cardiac disorders	Acute coronary syndrome	1	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	1	1
	Cardiac arrest	4	4	4	4
	Cardio-respiratory arrest	5	5	5	5
	Left ventricular dysfunction	2	2	2	2
	Myocardial infarction	1	1	1	1
	Pulseless electrical activity	1	1	1	1
	Tachycardia	1	1	1	1
	Ventricular arrhythmia	2	2	2	2
	SOC Subtotal	23	23	23	23
Congenital, familial and genetic disorders	Anencephaly	1	1	1	1
	SOC Subtotal	1	1	1	1



Canada Vigilance Summary of Product Adverse Reactions

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Health Product: See Search Criteria

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Seriousness: All

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

Total Number of Reports: 87

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Gastrointestinal disorders	Ascites	2	2	2	2
	Intestinal pseudo- obstruction	1	1	1	1
	Nausea	2	2	2	2
	Vomiting	1	1	1	1
SOC Subtotal		6	6	6	6
General disorders and administration site conditions	Accidental death	5	5	5	5
	Asthenia	1	1	1	1
	Death	10	10	10	10
	Death neonatal	1	1	1	1
	Drug interaction	21	21	21	21
	Fatigue	2	2	2	2
	Food interaction	2	2	2	2
	Hanging	1	1	1	1



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM
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: 87
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
General disorders and administration site conditions	Malaise	4	4	4	4
	Multiple organ dysfunction syndrome	1	1	1	1
	Oedema	1	1	1	1
	Potentiating drug interaction	2	2	2	2
	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
	SOC Subtotal	55	55	55	55
Hepatobiliary disorders	Hepatic cirrhosis	2	2	2	2
	SOC Subtotal	2	2	2	2



Canada Vigilance Summary of Product Adverse Reactions

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

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: 87

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

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



Canada Vigilance Summary of Product Adverse Reactions

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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: 87

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Injury, poisoning and procedural complications	Fall	3	3	3	3
	Head injury	1	1	1	1
	Heat stroke	1	1	1	1
	Incorrect route of product administration	1	1	1	1
	Intentional overdose	1	1	1	1
	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



Canada Vigilance Summary of Product Adverse Reactions

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

Total Number of Reports: 87

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Injury, poisoning and procedural complications	Pelvic fracture	1	1	1	1
	Poisoning	3	3	3	3
	Prescribed overdose	2	2	2	2
	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



Canada Vigilance Summary of Product Adverse Reactions

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

Health Product: See Search Criteria

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

Total Number of Reports: 87

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Investigations	Alcohol test positive	2	2	2	2
	Amphetamines positive	1	1	1	1
	Analgesic drug level above therapeutic	1	1	1	1
	Antidepressant drug level above therapeutic	3	3	3	3
	Benzodiazepine drug level therapeutic	1	1	1	1
	Blood ethanol increased	1	1	1	1
	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



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM
Health Product: See Search Criteria
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Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 87
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Metabolism and nutrition disorders	Decreased appetite	2	2	2	2
	Metabolic acidosis	1	1	1	1
	SOC Subtotal	3	3	3	3
Musculoskeletal and connective tissue disorders	Back pain	1	1	1	1
	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
	SOC Subtotal	2	2	2	2
Nervous system disorders	Brain injury	1	1	1	1
	Brain oedema	2	2	2	2
	Burning sensation	1	1	1	1
	Coma	1	1	1	1
	Depressed level of consciousness	1	1	1	1
	Dizziness	7	7	7	7



Canada Vigilance Summary of Product Adverse Reactions

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

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: 87

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Nervous system disorders	Haemorrhage intracranial	1	1	1	1
	Headache	1	1	1	1
	Hypoxic-ischaemic encephalopathy	2	2	2	2
	Ischaemic cerebral infarction	2	2	2	2
	Loss of consciousness	3	3	3	3
	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	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



Canada Vigilance Summary of Product Adverse Reactions

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

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: 87

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

		2021			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Psychiatric disorders	Anxiety	1	1	1	1
	Completed suicide	5	5	5	5
	Confusional state	4	4	4	4
	Depression	16	16	16	16
	Drug abuse	13	13	13	13
	Drug dependence	3	3	3	3
	Insomnia	1	1	1	1
	Mental disorder	2	2	2	2
	Psychiatric decompensation	1	1	1	1
	Sleep disorder	1	1	1	1
	Suicidal ideation	1	1	1	1
	Suicide attempt	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



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 3:11 PM
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: 87
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Respiratory, thoracic and mediastinal disorders	Asphyxia	2	2	2	2
	Asthma	2	2	2	2
	Hypoxia	1	1	1	1
	Oropharyngeal pain	1	1	1	1
	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	1



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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	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 medical procedures	Laparotomy	1	1	1	1
	Therapy change	2	2	2	2
	SOC Subtotal	3	3	3	3
Vascular disorders	Deep vein thrombosis	1	1	1	1
	Hypotension	2	2	2	2
	Pallor	1	1	1	1
	Shock	1	1	1	1
	SOC Subtotal	5	5	5	5
	Grand Total	325	325	325	325



Canada Vigilance Summary of Product Adverse Reactions

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 Occurrence	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 PAMOATE AMITRIPTYLIN Amitriptyline Pamoate Amitriptylin Amitriptyline hydrochloride Amitriptylinoxide amitriptylinoxide 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 occurred. The age is unknown in some of the adverse reaction reports and age specific searches will only include reports where the age is known.	AMITRIPTYLINE HYDROCHLORIDE AMITRIPTYLINE (CHLORHYDRATE D)
AR	Adverse Reaction	AMITRIPTYLINE HYDROCHLORIDE? PERPHENAZIN aripiprazole lauroxil
Gender	Gender of the patient as it was provided by the reporter. The gender is unknown in some of the adverse reaction reports and gender specific searches will not include reports where the gender is unknown.	dehydroaripiprazole aripiprazole
Health Product	A health product includes drugs and natural health 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.	aripiprazole (anhydrous) ARIPIPRAZOL aripiprazole caxoxil ARIPIPRAZOLE
Health Product Role	The characterization of the role of the product as provided by the original reporter of the adverse reaction. The health product role represents the opinion or observation of the individual reporter. Cause 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.	ARIPIPRAZOLE LAUROXIL Asenapine maleate asenapine Asenapine ASENAPINE Asenapine Maleate asenapine
HLT	High Level Term – see definition of MedDRA	ASENAPINE MALEATE
HLGT	High Level Group Term – see definition of MedDRA	asenapine
Initial Date of Receipt	The date that the first version of the adverse reaction report was received by Health Canada's Canada Vigilance Program.	ASENAPINE MALEATE asenapine maleate quetiapine
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.	quetiapine fumarate quetiapine quetiapine fumarate quetiapine quetiapine fumarate quetiapina
MedDRA Version	The MedDRA terminology is updated on a scheduled basis. The MedDRA version displayed reflects the version in use at the time of producing the summary.	QUETIAPINE quetiapine fumarate
NEC	Not Elsewhere Classified – MedDRA abbreviation	QUETIAPINA Cariprazine hydrochloride
NOS	Not Otherwise Specified – MedDRA abbreviation	Cariprazine Hydrochloride Cariprazine
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.	cariprazine hydrochloride CARIPRAZINE cariprazine
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.	CARIPRAZINE HYDROCHLORIDE chlorpromazine hibenzone Chlorpromazine
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.	CHLORPROMAZINE EMBONATE chlorpromazine phenolphthalinate CHLORPROMAZINE chlorpromazine CHLORPROMAZINE HYDROCHLORIDE Chlorpromazine Hydrochloride CHLORPROMAZINE HIBENZATE CHLORPROMAZINE PHENOLPHTHALINATE



Active Ingredient(s)	chlorpromazine embonate
	Chlorpromazine Embonate
	CHLORPROMAZINE TANNATE
	chlorpromazine hydrochloride
	CHLORPROMAZINE PROMETHAZINE COMBINED D
	CHLORPROMAZINE_PROMETHAZINE COMBINED D
	zuclopenthixol acetate
	ZUCLOPENTHIXOL DIHYDROCHLORIDE
	Zuclopenthixol Acetate
	ZUCLOPENTHIXOL
	zuclopenthixol
	ZUCLOPENTHIXOL DECANOATE
	zuclopenthixol hydrochloride
	ZUCLOPENTHIXOL ACETATE
	Zuclopenthixol Hydrochloride
	Zuclopenthixol
	zuclopenthixol decanoate
	zuclopenthixol dihydrochloride
	ZUCLOPENTHIXOL HYDROCHLORIDE
	Zuclopenthixol Decanoate
	clozapine
	Clozapine
	CLOZAPINE
	FLUPENTIXOL DIHYDROCHLORIDE
	Flupentixol
	flupentixol decanoate
	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
	Fluphenazine Hydrochloride
	fluphenazine enantate
	fluphenazine



	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 palmitate
	PALIPERIDONE PALMITATE
	Paliperidone palmitate
	paliperidone
	PALIPERIDONE
	lurasidone
	Lurasidone
	Lurasidone Hydrochloride
	lurasidone hydrochloride
	LURASIDONE
	LURASIDONE HYDROCHLORIDE
	Lurasidone hydrochloride
	LEVOMEPRMAZINE
	Levomepromazine Maleate
	LEVOMEPRMAZINE EMBONATE
	Levomepromazine Embonate
	LEVOMEPRMAZINE HYDROCHLORIDE
	levomepromazine embonate
	levomepromazine hydrochloride
	LEVOMEPRMAZINE MALEATE
	Levomepromazine Hydrochloride
	levomepromazine maleate
	levomepromazine
	Levomepromazine
	methotrimeprazine
	methotrimeprazine hydrochloride
	Periciazine
	PERICIAZINE
	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 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 TRANLYCYPROMINE SULFATE? TRIFLUOPERAZIN TRIFLUOPERAZINE/TRIFLUOPERAZINE HYDROCH TRIFLUOPERAZINE HYDROCHLORIDE
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	trifluoperazine trifluoperazine hydrochloride DESVENLAFAXINE SUCCINATE MONOHYDRATE desvenlafaxine Desvenlafaxine Desvenlafaxine succinate desvenlafaxine succinate desvenlafaxine succinate monohydrate DESVENLAFAXINE Desvenlafaxine Succinate desvenlafaxine fumarate 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

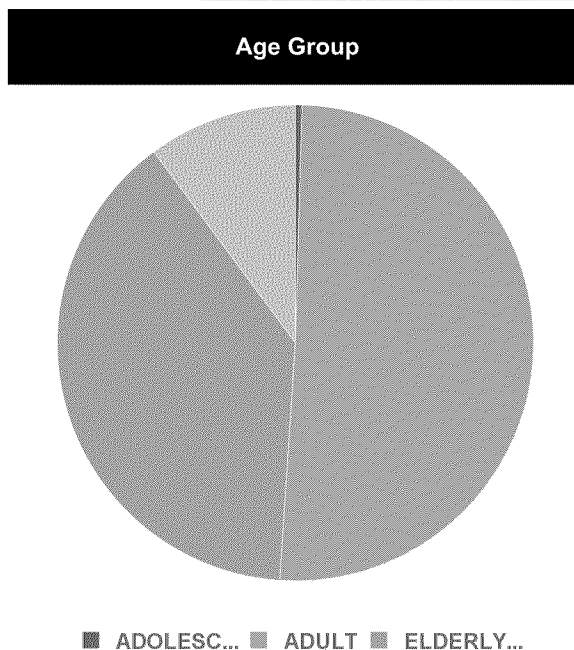
Report Runtime: 2022-02-15 2:27 PM
Health Product: See Search Criteria
Health Product Role:
Seriousness: All
Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 670
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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

Age Group		
ADOLESCENT	3	0.45%
ADULT	339	50.60%
ELDERLY	260	38.81%
UNKNOWN	68	10.15%

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



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

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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

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Foreign or Domestic: Domestic

System Organ Class	Number of All Reactions*	Number of Reactions* where outcome of report was fatal
HLGT		
HLT PT		

Blood and lymphatic system disorders

Anaemias nonhaemolytic and marrow depression

Marrow depression and hypoplastic anaemias	Pancytopenia	1	1
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Spleen, lymphatic and reticuloendothelial system disorders

Lymphatic system disorders NEC	Lymphadenopathy	3	3
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White blood cell disorders

Leukocytoses NEC	Leukocytosis	5	5
	Neutrophilia	4	4
Leukopenias NEC	Leukopenia	3	3
Neutropenias	Agranulocytosis	1	1
	Granulocytopenia	7	7
	Neutropenia	1	1

Blood and lymphatic system disorders SOC Total

		25	25
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Cardiac disorders

Cardiac arrhythmias

Cardiac conduction disorders	Bundle branch block right	1	1
Rate and rhythm disorders NEC	Arrhythmia	11	11
	Bradycardia	5	5
	Tachycardia	3	3
Supraventricular arrhythmias	Atrial fibrillation	2	2
	Sinus bradycardia	1	1

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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			
Cardiac disorders NEC	Acute cardiac event	1	1
	Cardiac disorder	4	4

Cardiac valve disorders			
Mitral valvular disorders	Mitral valve incompetence	1	1

Coronary artery disorders			
Coronary artery disorders NEC	Arteriosclerosis coronary artery	1	1
	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			
Heart failures NEC	Cardiac failure	10	10
	Cardiac failure chronic	1	1
	Cardiac failure congestive	1	1

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Gender: All
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Foreign or Domestic: Domestic

Myocardial disorders			
Myocardial disorders NEC	Cardiomegaly	1	1
	Left ventricular dysfunction	2	2
	Myocardial hypoxia	1	1
Noninfectious myocarditis	Myocarditis	4	4

Pericardial disorders			
Pericardial disorders NEC	Pericardial effusion	2	2

Cardiac disorders SOC Total		135	135
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Endocrine disorders			
Thyroid gland disorders			
Thyroid hypofunction disorders	Hypothyroidism	1	1

Endocrine disorders SOC Total		1	1
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Eye disorders			
Eye disorders NEC			
Lacrimation disorders	Lacrimation increased	1	1

Ocular neuromuscular disorders			
Pupil disorders	Pupil fixed	1	1

Eye disorders SOC Total		2	2
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Gastrointestinal disorders			
Abdominal hernias and other abdominal wall conditions			
Umbilical hernias	Umbilical hernia	3	3

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Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Gastrointestinal motility and defaecation conditions			
Gastrointestinal atonic and hypomotility disorders NEC	Constipation	1	1
	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

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Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Peritoneal and retroperitoneal conditions			
Peritoneal and retroperitoneal disorders	Ascites	3	3

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

Gastrointestinal disorders SOC Total		31	31
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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

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MedDRA Version:
Foreign or Domestic: Domestic

Gait disturbances	Gait inability	1	1
General signs and symptoms NEC	Condition aggravated	2	2
	General physical health deterioration	8	8
	Ill-defined disorder	1	1
	Illness	2	2
	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
Pain and discomfort NEC	Chest pain	2	2
	Pain	1	1

Therapeutic and nontherapeutic effects (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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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:	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

Therapeutic and nontherapeutic responses	Treatment noncompliance	5	5
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General disorders and administration site conditions SOC Total	583	583
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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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Canada Vigilance Summary of Product Adverse Reactions

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Total Number of Reports: 670
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Infections 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
Lower respiratory tract and lung infections	Pneumonia	22	22
	Pneumonia aspiration	10	10
	Pneumonia necrotising	1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	Bacteraemia	1	1
	Sepsis	2	2
	Urosepsis	2	2
Urinary tract infections	Kidney infection	1	1

Viral infectious disorders

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

Infections and infestations SOC Total

69 69

Injury, poisoning and procedural complications

Exposures, chemical injuries and poisoning

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Total Number of Reports: 670
Age: All
Gender: All
MedDRA Version:
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
Non-site specific injuries NEC	Fall	7	7
	Road traffic accident	1	1
Site specific injuries NEC	Head injury	4	3
Skin injuries NEC	Contusion	3	3

Medication errors and other product use errors and issues			
Medication errors, product use errors and issues NEC	Product use in unapproved indication	2	2
	Product use issue	1	1
Product administration errors and issues	Accidental overdose	2	2
	Contraindicated product administered	2	2
	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

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Product monitoring errors and issues	Labelled drug-drug interaction issue	3	3
	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			
Overdoses NEC	Intentional overdose	2	2
	Overdose	21	20
	Prescribed overdose	5	5
Underdoses NEC	Underdose	2	2

Procedural related injuries and complications NEC			
Non-site specific procedural complications	Iatrogenic injury	4	4

Injury, poisoning and procedural complications SOC Total	124	122
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Investigations			
Cardiac and vascular investigations (excl enzyme 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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Canada Vigilance Summary of Product Adverse Reactions

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Seriousness: All
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Total Number of Reports: 670
Age: All
Gender: All
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Foreign or Domestic: Domestic

White blood cell analyses	Neutrophil count increased	1	1
	White blood cell count increased	1	1

Investigations, imaging and histopathology procedures NEC			
Imaging procedures NEC	X-ray	1	1

Metabolic, nutritional and blood gas investigations			
Blood gas and acid base analyses	Oxygen saturation decreased	3	3

Neurological, special senses and psychiatric investigations			
Neurologic diagnostic procedures	Coma scale abnormal	1	1

Physical examination and organ system status topics			
Physical examination procedures and organ system status	Body temperature abnormal	1	1

Protein and chemistry analyses NEC			
Chemistry analyses NEC	Serum serotonin increased	1	1

Renal and urinary tract investigations and urinalyses			
Renal function analyses	Blood creatinine increased	1	1

Toxicology and therapeutic drug monitoring			
Therapeutic drug monitoring analyses	Analgesic drug level above therapeutic	1	1
	Antidepressant drug level above therapeutic	3	3
	Antipsychotic drug level decreased	4	4
	Benzodiazepine drug level therapeutic	1	1
Toxicology laboratory analyses	Alcohol test positive	2	2

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Toxicology laboratory analyses	Amphetamines positive	2	2
	Blood ethanol	1	1
	Blood ethanol increased	1	1
	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			
Mineral and electrolyte analyses	Blood phosphorus decreased	1	1
	Blood sodium decreased	1	1

Investigations SOC Total		59	59
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Metabolism and nutrition disorders

Appetite and general nutritional disorders

Appetite disorders	Decreased appetite	3	3
	Food refusal	1	1
General nutritional disorders NEC	Failure to thrive	1	1
	Malnutrition	1	1
	Starvation	1	1

Electrolyte and fluid balance conditions

Potassium imbalance	Hyperkalaemia	1	1
	Hypokalaemia	5	5
Sodium imbalance	Hypernatraemia	1	1
	Hyponatraemia	3	3
Total fluid volume decreased	Dehydration	3	3

Glucose metabolism disorders (incl diabetes mellitus)

Hyperglycaemic conditions NEC	Hyperglycaemia	1	1
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Metabolism and nutrition disorders SOC Total	21	21
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Musculoskeletal and connective tissue disorders

Muscle disorders			
Muscle pains	Myalgia	3	3
Muscle related signs and symptoms NEC	Muscle spasms	2	2
Muscle tone abnormalities	Muscle rigidity	1	1
	Trismus	1	1

Musculoskeletal and connective tissue disorders NEC

Musculoskeletal and connective tissue conditions NEC	Mobility decreased	1	1
	Musculoskeletal stiffness	2	2
Musculoskeletal and connective tissue infections and inflammations NEC	Fasciitis	1	1
Musculoskeletal and connective tissue pain and discomfort	Back pain	1	1
	Pain in extremity	1	1

Musculoskeletal and connective tissue disorders SOC Total	13	13
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Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Gastrointestinal neoplasms malignant and unspecified

Colorectal neoplasms malignant	Colorectal cancer metastatic	1	1
Pancreatic neoplasms malignant (excl islet cell and carcinoid)	Pancreatic carcinoma	2	2

Leukaemias

Leukaemias NEC	Leukaemia	1	1
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Lymphomas NEC

Lymphomas unspecified NEC	Lymphoma	1	1
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Lymphomas non-Hodgkin's B-cell			
B-cell lymphomas NEC	B-cell lymphoma	1	1
Mantle cell lymphomas	Mantle cell lymphoma	1	1

Metastases			
Metastases to specified sites	Metastases to liver	1	1

Miscellaneous and site unspecified neoplasms malignant and unspecified			
Neoplasms malignant site unspecified NEC	Metastatic neoplasm	2	2
	Neoplasm malignant	13	13

Nervous system neoplasms malignant and unspecified NEC			
Central nervous system neoplasms malignant NEC	Brain cancer metastatic	1	1
Glial tumours malignant	Glioblastoma	1	1
Nervous system neoplasms unspecified malignancy NEC	Brain neoplasm	1	1

Respiratory and mediastinal neoplasms malignant and unspecified			
Non-small cell neoplasms malignant of the respiratory tract cell type specified	Lung adenocarcinoma	1	1
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	Lung cancer metastatic	1	1
	Lung neoplasm malignant	10	10
Respiratory tract small cell carcinomas	Small cell lung cancer metastatic	1	1

ms benign, malignant and unspecified (incl cysts and polyps) SOC Total	39	39
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Nervous system disorders			
Central nervous system vascular disorders			
Central nervous system haemorrhages and cerebrovascular accidents	Cerebellar infarction	1	1

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Central nervous system haemorrhages and cerebrovascular accidents	Cerebral haemorrhage	1	1
	Cerebrovascular accident	4	4
	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			
Encephalopathies NEC	Encephalopathy	3	3
	Hypoxic-ischaemic encephalopathy	13	13
Encephalopathies toxic and metabolic	Hepatic encephalopathy	2	2

Headaches			
Headaches NEC	Headache	1	1

Increased intracranial pressure and hydrocephalus			
Increased intracranial pressure disorders	Brain oedema	2	2

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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Dyskinesias and movement disorders NEC	Dyskinesia	2	2
	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

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

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

Seizures (incl subtypes)

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Seizures and seizure disorders NEC	Epilepsy	1	1
	Seizure	5	5
	Status epilepticus	2	2

Structural brain disorders			
Structural brain disorders NEC	Brain injury	7	7

Nervous system disorders SOC Total		116	116
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Pregnancy, puerperium and perinatal conditions

Abortions and stillbirth			
Stillbirth and foetal death	Foetal death	2	2

Pregnancy, puerperium and perinatal conditions SOC Total		2	2
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Psychiatric disorders

Anxiety disorders and symptoms			
Anxiety symptoms	Agitation	8	8
	Anxiety	4	4

Changes in physical activity			
Stereotypies and automatisms	Posturing	1	1

Deliria (incl confusion)			
Confusion and disorientation	Confusional state	12	12
Deliria	Delirium	1	1

Depressed mood disorders and disturbances			
Depressive disorders	Depression	16	16

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Mood alterations with depressive symptoms	Depressed mood	1	1
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Disturbances in thinking and perception			
Delusional symptoms	Delusion of reference	1	1
Hallucinations (excl sleep-related)	Hallucination	5	5
	Hallucination, auditory	1	1

Personality disorders and disturbances in behaviour			
Behaviour and socialisation disturbances	Aggression	2	2

Psychiatric and behavioural symptoms NEC			
Abnormal behaviour NEC	Abnormal behaviour	1	1
Psychiatric symptoms NEC	Psychiatric decompensation	2	2

Psychiatric disorders NEC			
Mental disorders NEC	Mental disorder	2	2
Substance related and addictive disorders	Drug abuse	4	4
	Drug dependence	1	1

Schizophrenia and other psychotic disorders			
Psychotic disorder NEC	Psychotic disorder	5	5
Schizophrenia NEC	Schizophrenia	2	2

Sleep disorders and disturbances			
Disturbances in initiating and maintaining sleep	Insomnia	1	1
Sleep disorders NEC	Sleep disorder	1	1

Suicidal and self-injurious behaviours NEC			
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Suicidal and self-injurious behaviour	Assisted suicide	1	1
	Completed suicide	11	11
	Suicidal ideation	1	1

Psychiatric disorders SOC Total	84	84
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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

Urinary tract signs and symptoms

Bladder and urethral symptoms	Urinary incontinence	3	3
	Urinary retention	1	1

Renal and urinary disorders SOC Total	9	9
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Respiratory, thoracic and mediastinal disorders

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

Lower respiratory tract disorders (excl obstruction and infection)

Lower respiratory tract inflammatory and immunologic conditions	Pneumonitis	2	2
Pulmonary oedemas	Acute pulmonary oedema	5	5
	Acute respiratory distress syndrome	1	1
	Pulmonary congestion	2	2

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Pulmonary oedemas	Pulmonary oedema	1	1
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Pleural disorders			
Pneumothorax and pleural effusions NEC	Pleural effusion	2	2

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

Respiratory disorders NEC			
Breathing abnormalities	Dyspnoea	7	7
	Dyspnoea exertional	3	3
	Dyspnoea paroxysmal nocturnal	3	3
	Hypoventilation	1	1
	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 exchange	Asphyxia	3	3
	Hypoxia	4	4
Coughing and associated symptoms	Productive cough	3	3
	Sputum discoloured	3	3
Respiratory failures (excl neonatal)	Acute respiratory failure	1	1
	Respiratory failure	5	5
Respiratory tract disorders NEC	Aspiration	2	2
	Respiratory disorder	1	1

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

Respiratory, thoracic and mediastinal disorders SOC Total	85	85
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Skin and subcutaneous tissue disorders			
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 subcutaneous tissue disorders SOC Total	3	3
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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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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

Surgical and medical procedures

Gastrointestinal therapeutic procedures

Abdominal therapeutic procedures NEC	Laparotomy	1	1
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Psychiatric therapeutic procedures

Psychiatric therapies	Anxiolytic therapy	3	3
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Therapeutic procedures and supportive care NEC

Therapeutic procedures NEC	Drug therapy enhancement	3	3
	Hospitalisation	4	4
	Multiple drug therapy	3	3
	Surgery	1	1
	Therapy change	1	1

Surgical and medical procedures SOC Total

16	16
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Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Vascular disorders

Aneurysms and artery dissections

Aneurysms and dissections non-site specific	Aneurysm	1	1
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Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Non-site specific necrosis and vascular insufficiency NEC	Arteriosclerosis	2	2
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Decreased and nonspecific blood pressure disorders and shock

Circulatory collapse and shock	Circulatory collapse	1	1
Vascular hypotensive disorders	Hypotension	2	2

Embolism and thrombosis

Peripheral embolism and thrombosis	Deep vein thrombosis	4	4
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Vascular disorders NEC

Non-site specific vascular disorders NEC	Vasodilatation	1	1
Site specific vascular disorders NEC	Pallor	1	1

Vascular haemorrhagic disorders

Haemorrhages NEC	Internal haemorrhage	1	1
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Vascular hypertensive disorders

Vascular hypertensive disorders NEC	Hypertension	3	3
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Vascular disorders SOC Total

16 16

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		2021														
		January		February		March		April		May		June		July		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 and lymphatic system disorders	Agranulocytosis					1	1									
	Granulocytopenia			2	2			2	2	1	1					
	Leukocytosis							1	1					3	3	
	Leukopenia					2	2									
	Lymphadenopathy							1	1							2
	Neutropenia					1	1									
	Neutrophilia							1	1					2	2	
	Pancytopenia							1	1							
	SOC Subtotal			2	2	4	4	6	6	1	1			5	5	2

Cardiac disorders	Acute cardiac event													1	1	
	Acute coronary syndrome	1	1													
	Arrhythmia			1	1							1	1			1
	Arteriosclerosis coronary artery	1	1													
	Atrial fibrillation					1	1									
	Bradycardia			1	1					1	1					



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		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
Blood and lymphatic system disorders	Agranulocytosis										1	1
	Granulocytopenia						1	1	1	1	7	7
	Leukocytosis								1	1	5	5
	Leukopenia						1	1			3	3
	Lymphadenopathy	2									3	3
	Neutropenia										1	1
	Neutrophilia								1	1	4	4
	Pancytopenia										1	1
	SOC Subtotal	2					2	2	3	3	25	25

Cardiac disorders	Acute cardiac event										1	1
	Acute coronary syndrome		1	1							2	2
	Arrhythmia	1					1	1	7	7	11	11
	Arteriosclerosis coronary artery										1	1
	Atrial fibrillation								1	1	2	2
	Bradycardia		1	1			2	2			5	5



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		2021														
		January		February		March		April		May		June		July		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
Cardiac disorders	Bundle branch block right					1	1									
	Cardiac arrest			3	3	6	6			1	1	1	1	1	1	
	Cardiac disorder			1	1			1	1					1	1	
	Cardiac failure			1	1							1	1	2	2	1
	Cardiac failure chronic	1	1													
	Cardiac failure congestive									1	1					
	Cardiomegaly															
	Cardio-respiratory arrest															
	Coronary artery disease															
	Left ventricular dysfunction															
	Mitral valve incompetence													1	1	
	Myocardial hypoxia															
	Myocardial infarction	1	1	1	1	1	1	1	1			1	1	1	1	
	Myocardial ischaemia															
	Myocardial reperfusion injury															
	Myocarditis			1	1	1	1					1	1	1	1	
	Pericardial effusion			1	1							1	1			



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			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
Cardiac disorders	Bundle branch block right										1	1
	Cardiac arrest				3	3	2	2	8	8	25	25
	Cardiac disorder		1	1							4	4
	Cardiac failure	1	1	1					4	4	10	10
	Cardiac failure chronic										1	1
	Cardiac failure congestive										1	1
	Cardiomegaly								1	1	1	1
	Cardio-respiratory arrest								5	5	5	5
	Coronary artery disease		1	1							1	1
	Left ventricular dysfunction				1	1			1	1	2	2
	Mitral valve incompetence										1	1
	Myocardial hypoxia		1	1							1	1
	Myocardial infarction		1	1	1	1			2	2	10	10
	Myocardial ischaemia						1	1			1	1
	Myocardial reperfusion injury						1	1	7	7	8	8
	Myocarditis										4	4
	Pericardial effusion										2	2



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Seriousness: All
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Total Number of Reports: 670
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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		2021														
		January		February		March		April		May		June		July		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
Cardiac disorders	Pulseless electrical activity									1	1			1	1	
	Sinus bradycardia															
	Tachycardia			2	2	1	1									
	Torsade de pointes															
	Ventricular arrhythmia									1	1					2
	Ventricular fibrillation															
	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													
Eye disorders	Lacrimation increased			1	1											
	Pupil fixed			1	1											
	SOC Subtotal			2	2											
Gastrointestinal disorders	Anal incontinence			1	1											
	Ascites							1	1							
	Constipation					1	1									
	Discoloured vomit							1	1							



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		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
Cardiac disorders	Pulseless electrical activity										2	2
	Sinus bradycardia				1	1					1	1
	Tachycardia										3	3
	Torsade de pointes						2	2	10	10	12	12
	Ventricular arrhythmia	2							5	5	8	8
	Ventricular fibrillation		1	1			2	2	6	6	9	9
	SOC Subtotal	4	8	8	6	6	11	11	57	57	135	135
Endocrine disorders	Hypothyroidism										1	1
	SOC Subtotal										1	1
Eye disorders	Lacrimation increased										1	1
	Pupil fixed										1	1
	SOC Subtotal										2	2
Gastrointestinal disorders	Anal incontinence										1	1
	Ascites		1	1					1	1	3	3
	Constipation										1	1
	Discoloured vomit								1	1	2	2



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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
Gastrointestinal disorders	Faecaloma									1	1					
	Ileus					1	1									
	Intestinal dilatation					1	1									
	Intestinal ischaemia															1
	Intestinal obstruction					1	1									1
	Intestinal pseudo-obstruction					1	1									
	Large intestine perforation					1	1									
	Malignant gastrointestinal obstruction	1	1													
	Nausea			1	1							1	1			
	Odynophagia							1	1							2
	Salivary hypersecretion			1	1											
	Small intestinal obstruction							1	1					1	1	
	Umbilical hernia							1	1							2
	Vomiting															



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			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
Gastrointestinal disorders	Faecaloma				1	1					2	2
	Ileus										1	1
	Intestinal dilatation										1	1
	Intestinal ischaemia	1									1	1
	Intestinal obstruction	1									2	2
	Intestinal pseudo-obstruction										1	1
	Large intestine perforation										1	1
	Malignant gastrointestinal obstruction										1	1
	Nausea		1	1					1	1	4	4
	Odynophagia	2									3	3
	Salivary hypersecretion										1	1
	Small intestinal obstruction										2	2
	Umbilical hernia	2									3	3
	Vomiting									1	1	1



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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
	SOC Subtotal	1	1	3	3	6	6	5	5	1	1	1	1	1	1	6

General disorders and administration site conditions	Accidental death									1	1					2
	Asthenia			1	1	2	2									1
	Brain death															
	Chest pain													1	1	
	Condition aggravated			1	1											
	Death	48	48	34	34	25	25	37	37	33	33	22	22	60	60	52
	Drowning											1	1			
	Drug ineffective															
	Drug interaction			5	5			2	2	2	2	4	4			2
	Face oedema			1	1							1	1			



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		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
	SOC Subtotal	6	2	2	1	1			4	4	31	31

General disorders and administration site conditions	Accidental death	2	1	1			1	1	4	4	9	9
	Asthenia	1									4	4
	Brain death						2	2	7	7	9	9
	Chest pain		1	1							2	2
	Condition aggravated		1	1							2	2
	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	1	1	1	1	2	2	21	21
	Face oedema										2	2



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General disorders and administration site conditions	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
	Hanging					1	1									
	Hyperthermia			1	1											
	Hypothermia															
	Ill-defined disorder							1	1							
	Illness					1	1							1	1	
	Malaise					2	2	3	3							3



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		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
General disorders and administration site conditions	Fatigue		1	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
	Hanging										1	1
	Hyperthermia										1	1
	Hypothermia				1	1					1	1
	Ill-defined disorder										1	1
	Illness										2	2
	Malaise	3					1	1	1	1	10	10



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General disorders and administration site conditions	Mucosal dryness															
	Multiple organ dysfunction syndrome			1	1							1	1			
	Oedema															
	Oedema peripheral			1	1			1	1			1	1			2
	Organ failure															
	Pain															
	Paradoxical drug reaction															1
	Potentiating drug interaction															1
	Pyrexia	1	1	1	1	1	1	1	1					1	1	2
	Sudden cardiac death															



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			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
General disorders and administration site conditions	Mucosal dryness						1	1			1	1
	Multiple organ dysfunction syndrome								1	1	3	3
	Oedema						1	1			1	1
	Oedema peripheral	2									5	5
	Organ failure								1	1	1	1
	Pain		1	1							1	1
	Paradoxical drug reaction	1							3	3	4	4
	Potentiating drug interaction	1							1	1	2	2
	Pyrexia	2									7	7
	Sudden cardiac death								1	1	1	1



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		2021														
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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
General disorders and administration site conditions	Sudden death															
	Swelling			1	1							1	1			
	Temperature intolerance													1	1	
	Temperature regulation disorder			2	2											
	Terminal state											1	1			
	Therapeutic product effect incomplete															1
	Tobacco interaction					1	1									
	Treatment noncompliance			1	1	1	1	1	1			1	1			
	Unmasking of previously unidentified disease											1	1			
	SOC Subtotal	51	51	52	52	35	35	47	47	37	37	35	35	64	64	70



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		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
General disorders and administration site conditions	Sudden death		1	1							1	1
	Swelling										2	2
	Temperature intolerance										1	1
	Temperature regulation disorder										2	2
	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	1					2	2
SOC Subtotal		70	37	37	35	35	55	55	65	65	583	583



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Hepatobiliary disorders	Congestive hepatopathy			1	1							1	1			
	Hepatic cirrhosis							1	1							
	Hepatic failure			1	1	1	1					1	1			
	Hepatic steatosis															
	Hepatitis			1	1							1	1			
	Liver injury			1	1							1	1			
	SOC Subtotal			4	4	1	1	1	1			4	4			

Infections and infestations	Bacteraemia					1	1									
	Coronavirus infection	1	1	1	1											
	COVID-19	7	7			3	3	1	1					1	1	2
	COVID-19 pneumonia	3	3					1	1							2
	Endocarditis													1	1	
	Infection					1	1	1	1			1	1			
	Kidney infection															
	Pneumonia			1	1	3	3	2	2	1	1					4



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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
Hepatobiliary disorders	Congestive hepatopathy										2	2
	Hepatic cirrhosis								1	1	2	2
	Hepatic failure										3	3
	Hepatic steatosis								1	1	1	1
	Hepatitis										2	2
	Liver injury										2	2
	SOC Subtotal								2	2	12	12

Infections and infestations	Bacteraemia										1	1
	Coronavirus infection										2	2
	COVID-19	2									14	14
	COVID-19 pneumonia	2		1	1						7	7
	Endocarditis										1	1
	Infection										3	3
	Kidney infection		1	1							1	1
	Pneumonia	4		2	2	3	3	6	6		22	22



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		January		February		March		April		May		June		July		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
Infections and infestations	Pneumonia aspiration	2	2	1	1	1	1	1	1	2	2	2	2	1	1	
	Pneumonia necrotising											1	1			
	Sepsis					2	2									
	Staphylococcal infection					1	1									
	Stenotrophomonas infection					1	1									
	Suspected COVID-19					1	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	1	1									1	1			
	Brain herniation							1	1							
	Contraindicated product administered															
	Confusion							1	1							2



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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
Infections and infestations	Pneumonia aspiration										10	10
	Pneumonia necrotising										1	1
	Sepsis										2	2
	Staphylococcal infection										1	1
	Stenotrophomonas infection										1	1
	Suspected COVID-19										1	1
	Urosepsis	1									2	2
SOC Subtotal		9	1	1	3	3	3	3	6	6	69	69

Injury, poisoning and procedural complications	Accidental overdose										2	2
	Brain herniation		1	1					1	1	3	3
	Contraindicated product administered								2	2	2	2
	Contusion	2									3	3



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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
Injury, poisoning and procedural complications	Exposure during pregnancy															
	Exposure to extreme temperature			1	1									1	1	1
	Fall					2	2									1
	Head injury	1														1
	Heat stroke			1	1											2
	Iatrogenic injury															1
	Inappropriate schedule of product administration															1
	Incorrect route of product administration															
	Intentional overdose			1	1							1	1			
	Intentional product use issue									1	1					



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			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
Injury, poisoning and procedural complications	Exposure during pregnancy		1	1							1	1
	Exposure to extreme temperature	1									3	3
	Fall	1	1	1			2	2	1	1	7	7
	Head injury	1	2	2							4	3
	Heat stroke	2									3	3
	Iatrogenic injury	1							3	3	4	4
	Inappropriate schedule of product administration	1	1	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
 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: 670
 Age: All
 Gender: All
 MedDRA Version:
 Foreign or Domestic: Domestic

		2021														
		January		February		March		April		May		June		July		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
Injury, poisoning and procedural complications	Labelled drug-drug interaction issue															1
	Off label use	3	3	1	1	2	2	1	1	2	2	1	1	1	1	1
	Overdose			1	1	4	3			1	1	2	2			1
	Prescribed overdose									1	1					1
	Product communication issue															
	Product dispensing error															1
	Product dose omission issue			1	1											1
	Product monitoring error															
	Product use in unapproved indication	1	1													
	Product use issue															



Canada Vigilance Summary of Product Adverse Reactions

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Total Number of Reports: 670
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 Gender: All
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 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
Injury, poisoning and procedural complications	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	1	1	3	3	4	4	4	4	21	20
	Prescribed overdose	1	1	1					2	2	5	5
	Product communication issue		1	1							1	1
	Product dispensing error	1									1	1
	Product dose omission issue	1							2	2	4	4
	Product monitoring error		1	1							1	1
	Product use in unapproved indication				1	1					2	2
	Product use issue								1	1	1	1



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		2021														
		January		February		March		April		May		June		July		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
Injury, poisoning and procedural complications	Road traffic accident	1	1													
	Thermal burn															
	Toxicity to various agents			2	2	1	1	2	2			4	4	1	1	
	Underdose															
	Wrong patient received product															
SOC Subtotal		7	6	8	8	9	8	5	5	5	5	9	9	3	3	15

Investigations	Alcohol test positive			1	1							1	1			
	Amphetamines positive					1	1					1	1			
	Analgesic drug level above therapeutic															
	Antidepressant drug level above therapeutic															1
	Antipsychotic drug level decreased															1
	Benzodiazepine drug level therapeutic											1	1			



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		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
Injury, poisoning and procedural complications	Road traffic accident										1	1
	Thermal burn						1	1			1	1
	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							1	1
SOC Subtotal		15	13	13	9	9	11	11	30	30	124	122

Investigations	Alcohol test positive										2	2
	Amphetamines positive										2	2
	Analgesic drug level above therapeutic								1	1	1	1
	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



Canada Vigilance Summary of Product Adverse Reactions

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		2021														
		January		February		March		April		May		June		July		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
Investigations	Blood creatinine increased															
	Blood ethanol					1	1									
	Blood ethanol increased											1	1			
	Blood phosphorus decreased															
	Blood pressure decreased			1	1							1	1			
	Blood sodium decreased															
	Body temperature abnormal															
	Coma scale abnormal			1	1											
	Electrocardiogram QT prolonged															1
	Heart rate decreased															
	Neutrophil count increased													1	1	
	Opiates positive			1	1	1	1					3	3			
	Oxygen saturation decreased			1	1							1	1			
	Postmortem blood drug level					1	1							1	1	1
	Postmortem blood drug level increased											2	2			



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			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
Investigations	Blood creatinine increased						1	1			1	1
	Blood ethanol										1	1
	Blood ethanol increased										1	1
	Blood phosphorus decreased						1	1			1	1
	Blood pressure decreased										2	2
	Blood sodium decreased						1	1			1	1
	Body temperature abnormal						1	1			1	1
	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										5	5
	Oxygen saturation decreased		1	1							3	3
	Postmortem blood drug level	1							1	1	4	4
	Postmortem blood drug level increased										2	2



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: 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														
		January		February		March		April		May		June		July		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
Investigations	Serum serotonin increased									1	1					
	Toxicologic test abnormal			1	1			1	1			1	1			
	Troponin increased							1	1							2
	White blood cell count increased													1	1	
	X-ray					1	1									
	SOC Subtotal			6	6	5	5	2	2	1	1	12	12	3	3	6



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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

		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
Investigations	Serum serotonin increased										1	1
	Toxicologic test abnormal										3	3
	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



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		2021														
		January		February		March		April		May		June		July		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
Metabolism and nutrition disorders	Decreased appetite	1	1			1	1									
	Dehydration	1	1	1	1											1
	Failure to thrive															1
	Food refusal			1	1											
	Hyperglycaemia											1	1			
	Hyperkalaemia													1	1	
	Hypernatraemia									1	1					
	Hypokalaemia							1	1							2
	Hyponatraemia							1	1							2
	Malnutrition															1
	Starvation															
	SOC Subtotal	2	2	2	2	1	1	2	2	1	1	1	1	1	1	7



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		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
Metabolism and nutrition disorders	Decreased appetite								1	1	3	3
	Dehydration	1									3	3
	Failure to thrive	1									1	1
	Food refusal										1	1
	Hyperglycaemia										1	1
	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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		2021														
		January		February		March		April		May		June		July		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
Musculoskeletal and connective tissue disorders	Back pain															
	Fasciitis					1	1									
	Mobility decreased					1	1									
	Muscle rigidity			1	1											
	Muscle spasms			1	1							1	1			
	Musculoskeletal stiffness			1	1							1	1			
	Myalgia			1	1	1	1					1	1			
	Pain in extremity			1	1											
	Trismus			1	1											
	SOC Subtotal			6	6	3	3					3	3			



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		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
Musculoskeletal and connective tissue disorders	Back pain		1	1							1	1
	Fasciitis										1	1
	Mobility decreased										1	1
	Muscle rigidity										1	1
	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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		2021														
		January		February		March		April		May		June		July		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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	B-cell lymphoma							1	1							
	Brain cancer metastatic															
	Brain neoplasm	1	1													
	Colorectal cancer metastatic															
	Glioblastoma															
	Leukaemia													1	1	
	Lung adenocarcinoma															
	Lung cancer metastatic															1



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		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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	B-cell lymphoma										1	1
	Brain cancer metastatic								1	1	1	1
	Brain neoplasm										1	1
	Colorectal cancer metastatic								1	1	1	1
	Glioblastoma								1	1	1	1
	Leukaemia										1	1
	Lung adenocarcinoma						1	1			1	1
	Lung cancer metastatic	1									1	1



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		2021														
		January		February		March		April		May		June		July		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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant									3	3			2	2	2
	Lymphoma							1	1							
	Mantle cell lymphoma															1
	Metastases to liver															
	Metastatic neoplasm	1	1	1	1											
	Neoplasm malignant	1	1	1	1	2	2	2	2					1	1	
	Pancreatic carcinoma															
	Small cell lung cancer metastatic	1	1													
	SOC Subtotal	4	4	2	2	2	2	4	4	3	3			4	4	4



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		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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	2					1	1	2	2	10	10
	Lymphoma										1	1
	Mantle cell lymphoma	1									1	1
	Metastases to liver								1	1	1	1
	Metastatic neoplasm										2	2
	Neoplasm malignant		1	1	1	1	3	3	1	1	13	13
	Pancreatic carcinoma						1	1	1	1	2	2
	Small cell lung cancer metastatic										1	1
SOC Subtotal		4	1	1	1	1	6	6	8	8	39	39



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		2021														
		January		February		March		April		May		June		July		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
Nervous system disorders	Apallic syndrome															
	Brain injury									1	1					
	Brain oedema							1	1							
	Cerebellar infarction															1
	Cerebral amyloid angiopathy											1	1			
	Cerebral haemorrhage															1
	Cerebrovascular accident			1	1	1	1									
	Clonus															
	Coma															
	Dementia									1	1					1
	Dementia Alzheimer's type											1	1			
	Depressed level of consciousness			1	1					1	1	1	1			
	Dizziness															
	Dyskinesia											1	1			



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		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
Nervous system disorders	Apallic syndrome						1	1			1	1
	Brain injury						1	1	5	5	7	7
	Brain oedema								1	1	2	2
	Cerebellar infarction	1									1	1
	Cerebral amyloid angiopathy				1	1					2	2
	Cerebral haemorrhage	1									1	1
	Cerebrovascular accident		2	2							4	4
	Clonus				1	1					1	1
	Coma		1	1							1	1
	Dementia	1	1	1			1	1	1	1	5	5
	Dementia Alzheimer's type				1	1					2	2
	Depressed level of consciousness										3	3
	Dizziness						1	1			1	1
	Dyskinesia				1	1					2	2



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		2021														
		January		February		March		April		May		June		July		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
Nervous system disorders	Encephalopathy			1	1	1	1					1	1			
	Epilepsy															
	Frontotemporal dementia															
	Haemorrhage intracranial															
	Headache															
	Hepatic encephalopathy			1	1							1	1			
	Hypotonia			1	1											
	Hypoxic-ischaemic encephalopathy															
	Ischaemic cerebral infarction							1	1							
	Ischaemic stroke	1	1													
	Lethargy															1
	Loss of consciousness			1	1					1	1	1	1			
	Mental impairment															1
	Myoclonus							1	1							2



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		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
Nervous system disorders	Encephalopathy										3	3
	Epilepsy								1	1	1	1
	Frontotemporal dementia						1	1			1	1
	Haemorrhage intracranial		1	1							1	1
	Headache		1	1							1	1
	Hepatic encephalopathy										2	2
	Hypotonia										1	1
	Hypoxic-ischaemic encephalopathy				1	1	2	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	1			1	1	5	5
	Mental impairment	1							1	1	2	2
	Myoclonus	2									3	3



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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:27 PM
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: 670
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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		2021														
		January		February		March		April		May		June		July		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
Nervous system disorders	Neuralgia							1	1							2
	Neuroleptic malignant syndrome			1	1											
	Neurotoxicity							1	1							2
	Paralysis	1	1													
	Parkinsonism					1	1					1	1			
	Parkinson's disease					1	1			1	1	1	1			
	Seizure	1	1	1	1	1	1					1	1			
	Serotonin syndrome							1	1							
	Somnolence			1	1			1	1					1	1	3
	Speech disorder			2	2							1	1			
	Status epilepticus															
	Tardive dyskinesia											1	1			
	Tremor							1	1							2
	Unresponsive to stimuli															



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		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
Nervous system disorders	Neuralgia	2									3	3
	Neuroleptic malignant syndrome				1	1					2	2
	Neurotoxicity	2									3	3
	Paralysis										1	1
	Parkinsonism				1	1					3	3
	Parkinson's disease								1	1	4	4
	Seizure				1	1					5	5
	Serotonin syndrome								1	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				1	1					2	2
	Tremor	2							1	1	4	4
	Unresponsive to stimuli								1	1	1	1



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		2021														
		January		February		March		April		May		June		July		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
Nervous system disorders	Vascular dementia	1	1													
	SOC Subtotal	4	4	11	11	5	5	8	8	5	5	12	12	1	1	16

Pregnancy, puerperium and perinatal conditions	Foetal death															
	SOC Subtotal															

Psychiatric disorders	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	1	1	1	1	1	1	1	2	2			
	Confusional state			2	2	1	1	1	1			2	2			3
	Delirium									1	1					
	Delusion of reference															
	Depressed mood															
	Depression			4	4			2	2	1	1	4	4			1
	Drug abuse			1	1	1	1					1	1	1	1	
	Drug dependence															
	Hallucination							1	1			1	1			2



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		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
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

Psychiatric disorders	Abnormal behaviour										1	1
	Aggression										2	2
	Agitation	1	1	1					3	3	8	8
	Anxiety	2	1	1							4	4
	Assisted suicide										1	1
	Completed suicide		1	1	1	1	2	2			11	11
	Confusional state	3	1	1	1	1			1	1	12	12
	Delirium										1	1
	Delusion of reference						1	1			1	1
	Depressed mood		1	1							1	1
	Depression	1	2	2	1	1	1	1			16	16
	Drug abuse										4	4
	Drug dependence								1	1	1	1
	Hallucination	2			1	1					5	5



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		2021														
		January		February		March		April		May		June		July		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
Psychiatric disorders	Hallucination, auditory															
	Insomnia	1	1													
	Mental disorder					1	1	1	1							
	Posturing			1	1											
	Psychiatric decompensation									1	1			1	1	
	Psychotic disorder	1	1													1
	Schizophrenia			1	1					1	1					
	Sleep disorder															
	Suicidal ideation	1	1													
	SOC Subtotal	6	6	12	12	5	5	8	8	5	5	11	11	2	2	10

Renal and urinary disorders	Renal disorder			1	1	1	1					1	1			
	Renal failure															1
	Renal tubular necrosis					1	1									
	Urinary incontinence							1	1							2
	Urinary retention							1	1							
	SOC Subtotal			1	1	2	2	2	2			1	1			3



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		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
Psychiatric disorders	Hallucination, auditory								1	1	1	1
	Insomnia										1	1
	Mental disorder										2	2
	Posturing										1	1
	Psychiatric decompensation										2	2
	Psychotic disorder	1							3	3	5	5
	Schizophrenia										2	2
	Sleep disorder								1	1	1	1
	Suicidal ideation										1	1
SOC Subtotal		10	7	7	4	4	4	4	10	10	84	84

Renal and urinary disorders	Renal disorder										3	3
	Renal failure	1									1	1
	Renal tubular necrosis										1	1
	Urinary incontinence	2									3	3
	Urinary retention										1	1
SOC Subtotal		3									9	9



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		2021														
		January		February		March		April		May		June		July		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
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema															1
	Acute respiratory distress syndrome	1	1													
	Acute respiratory failure	1	1													
	Asphyxia											2	2			1
	Aspiration													1	1	
	Choking			1	1					1	1	1	1	2	2	
	Chronic obstructive pulmonary disease	1	1													
	Dyspnoea							1	1					1	1	3
	Dyspnoea exertional							1	1							2
	Dyspnoea paroxysmal nocturnal							1	1							2



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		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
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	1	1					3	3	5	5
	Acute respiratory distress syndrome										1	1
	Acute respiratory failure										1	1
	Asphyxia	1									3	3
	Aspiration				1	1					2	2
	Choking		1	1							6	6
	Chronic obstructive pulmonary disease						1	1			2	2
	Dyspnoea	3	1	1					1	1	7	7
	Dyspnoea exertional	2									3	3
	Dyspnoea paroxysmal nocturnal	2									3	3



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		2021														
		January		February		March		April		May		June		July		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
Respiratory, thoracic and mediastinal disorders	Hypoventilation															
	Hypoxia					1	1	1	1							2
	Oropharyngeal pain															
	Orthopnoea							1	1							2
	Pleural effusion			1	1							1	1			
	Pneumonitis															
	Productive cough							1	1							2
	Pulmonary congestion															
	Pulmonary embolism					1	1	1	1	2	2					2
	Pulmonary oedema															



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			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
Respiratory, thoracic and mediastinal disorders	Hypoventilation		1	1							1	1
	Hypoxia	2									4	4
	Oropharyngeal pain								1	1	1	1
	Orthopnoea	2									3	3
	Pleural effusion										2	2
	Pneumonitis				1	1			1	1	2	2
	Productive cough	2									3	3
	Pulmonary congestion						1	1	1	1	2	2
	Pulmonary embolism	2					1	1	5	5	12	12
	Pulmonary oedema						1	1			1	1



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		2021														
		January		February		March		April		May		June		July		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
Respiratory, thoracic and mediastinal disorders	Respiratory arrest															
	Respiratory depression															1
	Respiratory disorder															
	Respiratory distress															
	Respiratory failure					1	1	1	1					1	1	2
	Rhinorrhoea							1	1							2
	Sleep apnoea syndrome															1
	Sputum discoloured							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



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		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
Respiratory, thoracic and mediastinal disorders	Respiratory arrest								1	1	1	1
	Respiratory depression	1							1	1	2	2
	Respiratory disorder				1	1					1	1
	Respiratory distress		1	1							1	1
	Respiratory failure	2									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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		2021														
		January		February		March		April		May		June		July		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 tissue disorders	Dermal cyst													1	1	
	Hyperhidrosis			1	1											
	Skin disorder															
	SOC Subtotal			1	1									1	1	
Social circumstances										1	1					
	SOC Subtotal									1	1					



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		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
Skin and subcutaneous tissue disorders	Dermal cyst										1	1
	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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		2021														
		January		February		March		April		May		June		July		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
Surgical and medical procedures	Anxiolytic therapy															1
	Drug therapy enhancement															1
	Hospitalisation							1	1					1	1	
	Laparotomy					1	1									
	Multiple drug therapy															1
	Surgery					1	1									
	Therapy change									1	1					
	SOC Subtotal					2	2	1	1	1	1			1	1	3



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		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
Surgical and medical procedures	Anxiolytic therapy	1							2	2	3	3
	Drug therapy enhancement	1							2	2	3	3
	Hospitalisation						2	2			4	4
	Laparotomy										1	1
	Multiple drug therapy	1							2	2	3	3
	Surgery										1	1
	Therapy change										1	1
	SOC Subtotal	3					2	2	6	6	16	16



Canada Vigilance Summary of Product Adverse Reactions

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 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														
		January		February		March		April		May		June		July		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
Vascular disorders	Aneurysm															
	Arteriosclerosis	1	1									1	1			
	Circulatory collapse					1	1									
	Deep vein thrombosis							1	1	1	1					2
	Hypertension	1	1													
	Hypotension					1	1			1	1					
	Internal haemorrhage															
	Pallor					1	1									
	Vasodilatation			1	1											
	SOC Subtotal	2	2	1	1	3	3	1	1	2	2	1	1			2
	Grand Total	98	97	130	130	112	111	111	111	75	75	104	104	103	103	184



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		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
Vascular disorders	Aneurysm				1	1					1	1
	Arteriosclerosis										2	2
	Circulatory collapse										1	1
	Deep vein thrombosis	2									4	4
	Hypertension						1	1	1	1	3	3
	Hypotension										2	2
	Internal haemorrhage								1	1	1	1
	Pallor										1	1
	Vasodilatation										1	1
	SOC Subtotal	2			1	1	1	1	2	2	16	16
	Grand Total	184	87	87	77	77	116	116	252	252	1,449	1,447



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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: 670

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Blood and lymphatic system disorders	Agranulocytosis	1	1	1	1
	Granulocytopenia	7	7	7	7
	Leukocytosis	5	5	5	5
	Leukopenia	3	3	3	3
	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
Cardiac disorders	Acute cardiac event	1	1	1	1
	Acute coronary syndrome	2	2	2	2
	Arrhythmia	11	11	11	11
	Arteriosclerosis coronary artery	1	1	1	1



Canada Vigilance Summary of Product Adverse Reactions

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

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: 670

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Cardiac disorders	Atrial fibrillation	2	2	2	2
	Bradycardia	5	5	5	5
	Bundle branch block right	1	1	1	1
	Cardiac arrest	25	25	25	25
	Cardiac disorder	4	4	4	4
	Cardiac failure	10	10	10	10
	Cardiac failure chronic	1	1	1	1
	Cardiac failure congestive	1	1	1	1
	Cardiomegaly	1	1	1	1
	Cardio-respiratory arrest	5	5	5	5
	Coronary artery disease	1	1	1	1
	Left ventricular dysfunction	2	2	2	2
	Mitral valve incompetence	1	1	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



Canada Vigilance Summary of Product Adverse Reactions

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

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: 670

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Cardiac disorders	Pericardial effusion	2	2	2	2
	Pulseless electrical activity	2	2	2	2
	Sinus bradycardia	1	1	1	1
	Tachycardia	3	3	3	3
	Torsade de pointes	12	12	12	12
	Ventricular arrhythmia	8	8	8	8
	Ventricular fibrillation	9	9	9	9
	SOC Subtotal	135	135	135	135
Endocrine disorders	Hypothyroidism	1	1	1	1
	SOC Subtotal	1	1	1	1
Eye disorders	Lacrimation increased	1	1	1	1
	Pupil fixed	1	1	1	1
	SOC Subtotal	2	2	2	2
Gastrointestinal disorders	Anal incontinence	1	1	1	1
	Ascites	3	3	3	3
	Constipation	1	1	1	1
	Discoloured vomit	2	2	2	2
	Faecaloma	2	2	2	2



Canada Vigilance Summary of Product Adverse Reactions

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Gastrointestinal disorders	Ileus	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	1
	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	1
SOC Subtotal		31	31	31	31



Canada Vigilance Summary of Product Adverse Reactions

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
General disorders and administration site conditions	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
	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



Canada Vigilance Summary of Product Adverse Reactions

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
General disorders and administration site conditions	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
	Hypothermia	1	1	1	1
	Ill-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



Canada Vigilance Summary of Product Adverse Reactions

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Health Product: See Search Criteria

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
General disorders and administration site conditions	Oedema	1	1	1	1
	Oedema peripheral	5	5	5	5
	Organ failure	1	1	1	1
	Pain	1	1	1	1
	Paradoxical drug reaction	4	4	4	4
	Potentiating drug interaction	2	2	2	2
	Pyrexia	7	7	7	7
	Sudden cardiac death	1	1	1	1
	Sudden death	1	1	1	1
	Swelling	2	2	2	2
	Temperature intolerance	1	1	1	1



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:27 PM
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: 670
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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



Canada Vigilance Summary of Product Adverse Reactions

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 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: 670
 Age: All
 Gender: All
 MedDRA Version:
 Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Hepatobiliary disorders	Congestive hepatopathy	2	2	2	2
	Hepatic cirrhosis	2	2	2	2
	Hepatic failure	3	3	3	3
	Hepatic steatosis	1	1	1	1
	Hepatitis	2	2	2	2
	Liver injury	2	2	2	2
SOC Subtotal		12	12	12	12
Infections and infestations	Bacteraemia	1	1	1	1
	Coronavirus infection	2	2	2	2
	COVID-19	14	14	14	14
	COVID-19 pneumonia	7	7	7	7
	Endocarditis	1	1	1	1
	Infection	3	3	3	3
	Kidney infection	1	1	1	1
	Pneumonia	22	22	22	22



Canada Vigilance Summary of Product Adverse Reactions

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 Health Product: See Search Criteria
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Total Number of Reports: 670
 Age: All
 Gender: All
 MedDRA Version:
 Foreign or Domestic: Domestic

		2021			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Infections and infestations	Pneumonia aspiration	10	10	10	10
	Pneumonia necrotising	1	1	1	1
	Sepsis	2	2	2	2
	Staphylococcal infection	1	1	1	1
	Stenotrophomonas infection	1	1	1	1
	Suspected COVID-19	1	1	1	1
	Urosepsis	2	2	2	2
SOC Subtotal		69	69	69	69
Injury, poisoning and procedural complications	Accidental overdose	2	2	2	2
	Brain herniation	3	3	3	3
	Contraindicated product administered	2	2	2	2
	Contusion	3	3	3	3
	Exposure during pregnancy	1	1	1	1



Canada Vigilance Summary of Product Adverse Reactions

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Health Product: See Search Criteria

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Injury, poisoning and procedural complications	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
	Iatrogenic injury	4	4	4	4
	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	3
	Off label use	22	22	22	22



Canada Vigilance Summary of Product Adverse Reactions

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Health Product: See Search Criteria

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Injury, poisoning and procedural complications	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
	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



Canada Vigilance Summary of Product Adverse Reactions

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Injury, poisoning and procedural complications	Underdose	2	2	2	2
	Wrong patient received product	1	1	1	1
	SOC Subtotal	124	122	124	122
Investigations	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
	Benzodiazepine drug level therapeutic	1	1	1	1
	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	1	1
	Blood pressure decreased	2	2	2	2
	Blood sodium decreased	1	1	1	1



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Health Product: See Search Criteria

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Investigations	Body temperature abnormal	1	1	1	1
	Coma scale abnormal	1	1	1	1
	Electrocardiogram QT prolonged	12	12	12	12
	Heart rate decreased	1	1	1	1
	Neutrophil count increased	1	1	1	1
	Opiates positive	5	5	5	5
	Oxygen saturation decreased	3	3	3	3
	Postmortem blood drug level	4	4	4	4
	Postmortem blood drug level increased	2	2	2	2
	Serum serotonin increased	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



Canada Vigilance Summary of Product Adverse Reactions

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Health Product: See Search Criteria

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Metabolism and nutrition disorders	Decreased appetite	3	3	3	3
	Dehydration	3	3	3	3
	Failure to thrive	1	1	1	1
	Food refusal	1	1	1	1
	Hyperglycaemia	1	1	1	1
	Hyperkalaemia	1	1	1	1
	Hypernatraemia	1	1	1	1
	Hypokalaemia	5	5	5	5
	Hyponatraemia	3	3	3	3
	Malnutrition	1	1	1	1
	Starvation	1	1	1	1
	SOC Subtotal	21	21	21	21



Canada Vigilance Summary of Product Adverse Reactions

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Health Product: See Search Criteria

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Musculoskeletal and connective tissue disorders	Back pain	1	1	1	1
	Fasciitis	1	1	1	1
	Mobility decreased	1	1	1	1
	Muscle rigidity	1	1	1	1
	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	1
	SOC Subtotal	13	13	13	13
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	B-cell lymphoma	1	1	1	1



Canada Vigilance Summary of Product Adverse Reactions

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain cancer metastatic	1	1	1	1
	Brain neoplasm	1	1	1	1
	Colorectal cancer metastatic	1	1	1	1
	Glioblastoma	1	1	1	1
	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	1	1



Canada Vigilance Summary of Product Adverse Reactions

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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

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



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Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Nervous system disorders	Cerebral amyloid angiopathy	2	2	2	2
	Cerebral haemorrhage	1	1	1	1
	Cerebrovascular accident	4	4	4	4
	Clonus	1	1	1	1
	Coma	1	1	1	1
	Dementia	5	5	5	5
	Dementia Alzheimer's type	2	2	2	2
	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	1	1	1
	Frontotemporal dementia	1	1	1	1
	Haemorrhage intracranial	1	1	1	1
	Headache	1	1	1	1



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Age: All

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MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Nervous system disorders	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	1	1	1
	Lethargy	2	2	2	2
	Loss of consciousness	5	5	5	5
	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	1	1	1	1
	Parkinsonism	3	3	3	3
	Parkinson's disease	4	4	4	4



Canada Vigilance Summary of Product Adverse Reactions

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MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Nervous system disorders	Seizure	5	5	5	5
	Serotonin syndrome	2	2	2	2
	Somnolence	9	9	9	9
	Speech disorder	3	3	3	3
	Status epilepticus	2	2	2	2
	Tardive dyskinesia	2	2	2	2
	Tremor	4	4	4	4
	Unresponsive to stimuli	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
	SOC Subtotal	2	2	2	2
Psychiatric disorders	Abnormal behaviour	1	1	1	1
	Aggression	2	2	2	2
	Agitation	8	8	8	8



Canada Vigilance Summary of Product Adverse Reactions

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Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Psychiatric disorders	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
	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	1	1	1
	Mental disorder	2	2	2	2
	Posturing	1	1	1	1



Canada Vigilance Summary of Product Adverse Reactions

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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Psychiatric disorders	Psychiatric decompensation	2	2	2	2
	Psychotic disorder	5	5	5	5
	Schizophrenia	2	2	2	2
	Sleep disorder	1	1	1	1
	Suicidal ideation	1	1	1	1
	SOC Subtotal	84	84	84	84
Renal and urinary disorders	Renal disorder	3	3	3	3
	Renal failure	1	1	1	1
	Renal tubular necrosis	1	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	1	1	1	1



Canada Vigilance Summary of Product Adverse Reactions

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

Total Number of Reports: 670

Age: All

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MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	1	1	1	1
	Asphyxia	3	3	3	3
	Aspiration	2	2	2	2
	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



Canada Vigilance Summary of Product Adverse Reactions

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Health Product Role:
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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Respiratory, thoracic and mediastinal disorders	Hypoxia	4	4	4	4
	Oropharyngeal pain	1	1	1	1
	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



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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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	1	1	1	1
	Respiratory depression	2	2	2	2
	Respiratory disorder	1	1	1	1
	Respiratory distress	1	1	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



Canada Vigilance Summary of Product Adverse Reactions

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

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: 670

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
	SOC Subtotal	85	85	85	85
Skin and subcutaneous tissue disorders	Dermal cyst	1	1	1	1
	Hyperhidrosis	1	1	1	1
	Skin disorder	1	1	1	1
	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
Surgical and medical procedures	Anxiolytic therapy	3	3	3	3
	Drug therapy enhancement	3	3	3	3
	Hospitalisation	4	4	4	4
	Laparotomy	1	1	1	1
	Multiple drug therapy	3	3	3	3
	Surgery	1	1	1	1
	Therapy change	1	1	1	1
	SOC Subtotal	16	16	16	16



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:	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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Vascular disorders	Aneurysm	1	1	1	1
	Arteriosclerosis	2	2	2	2
	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



Canada Vigilance

Summary of Product Adverse Reactions

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 Occurrence	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 PAMOATE AMITRIPTYLIN Amitriptyline Pamoate Amitriptylin Amitriptyline hydrochloride Amitriptylinoxide amitriptylinoxide 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 occurred. The age is unknown in some of the adverse reaction reports and age specific searches will only include reports where the age is known.
	AR	Adverse Reaction
	Gender	Gender of the patient as it was provided by the reporter. The gender is unknown in some of the adverse reaction reports and gender specific searches will not include reports where the gender is unknown.
	Health Product	A health product includes drugs and natural health 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 Role	The characterization of the role of the product as provided by the original reporter of the adverse reaction. The health product role represents the opinion or observation of the individual reporter. Cause 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.
	HLT	High Level Term – see definition of MedDRA
	HLGT	High Level Group Term – see definition of MedDRA
	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 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.



Active Ingredient(s)	chlorpromazine embonate
	Chlorpromazine Embonate
	CHLORPROMAZINE TANNATE
	chlorpromazine hydrochloride
	CHLORPROMAZINE PROMETHAZINE COMBINED D
	CHLORPROMAZINE_PROMETHAZINE COMBINED D
	zuclopenthixol acetate
	ZUCLOPENTHIXOL DIHYDROCHLORIDE
	Zuclopenthixol Acetate
	ZUCLOPENTHIXOL
	zuclopenthixol
	ZUCLOPENTHIXOL DECANOATE
	zuclopenthixol hydrochloride
	ZUCLOPENTHIXOL ACETATE
	Zuclopenthixol Hydrochloride
	Zuclopenthixol
	zuclopenthixol decanoate
	zuclopenthixol dihydrochloride
	ZUCLOPENTHIXOL HYDROCHLORIDE
	Zuclopenthixol Decanoate
	clozapine
	Clozapine
	CLOZAPINE
	FLUPENTIXOL DIHYDROCHLORIDE
	Flupentixol
	flupentixol decanoate
	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
	Fluphenazine Hydrochloride
	fluphenazine enantate
	fluphenazine



	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 palmitate
	PALIPERIDONE PALMITATE
	Paliperidone palmitate
	paliperidone
	PALIPERIDONE
	lurasidone
	Lurasidone
	Lurasidone Hydrochloride
	lurasidone hydrochloride
	LURASIDONE
	LURASIDONE HYDROCHLORIDE
	Lurasidone hydrochloride
	LEVOMEPRMAZINE
	Levomepromazine Maleate
	LEVOMEPRMAZINE EMBONATE
	Levomepromazine Embonate
	LEVOMEPRMAZINE HYDROCHLORIDE
	levomepromazine embonate
	levomepromazine hydrochloride
	LEVOMEPRMAZINE MALEATE
	Levomepromazine Hydrochloride
	levomepromazine maleate
	levomepromazine
	Levomepromazine
	methotrimeprazine
	methotrimeprazine hydrochloride
	Periciazine
	PERICIAZINE
	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
	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
	TRANLYCYPROMINE SULFATE? TRIFLUOPERAZIN
	TRIFLUOPERAZINE/TRIFLUOPERAZINE HYDROCH
	TRIFLUOPERAZINE HYDROCHLORIDE



	trifluoperazine trifluoperazine hydrochloride DESVENLAFAXINE SUCCINATE MONOHYDRATE desvenlafaxine Desvenlafaxine Desvenlafaxine succinate desvenlafaxine succinate desvenlafaxine succinate monohydrate DESVENLAFAXINE Desvenlafaxine Succinate desvenlafaxine fumarate 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 Suicide threat Suspected suicide



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Canada Vigilance Summary of Product Adverse Reactions

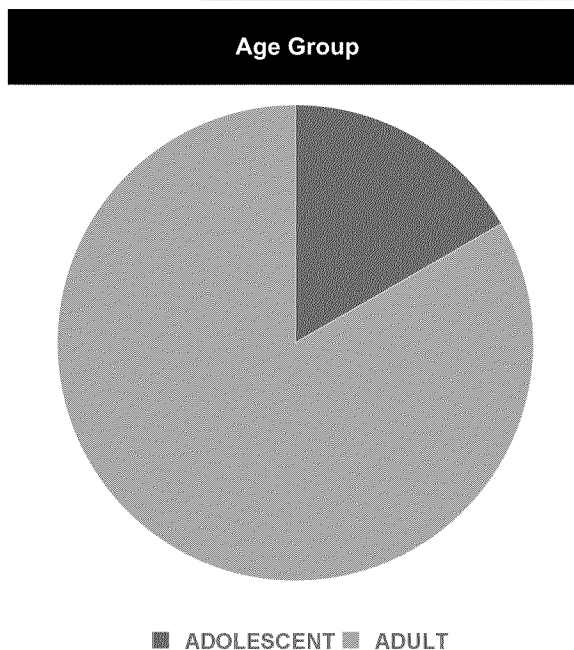
Report Runtime: 2022-02-15 2:52 PM
Health Product: See Search Criteria
Health Product Role:
Seriousness: All
Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 12
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousness	
69	12	12	Death	12
			Life Threatening	2
			Hospitalization required	2
			Disability	0
			Congenital Anomaly	0
			Other Medically Important Condition	4

Age Group		
ADOLESCENT	2	16.67%
ADULT	10	83.33%

Patient Sex		
Female	4	33.33%
Male	8	66.67%



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

Report Runtime: 2022-02-15 2:52 PM
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: 12
Age: All
Gender: All
MedDRA Version:
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

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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM
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: 12
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

System Organ Class	Number of All Reactions*	Number of Reactions* where outcome of report was fatal
HLGT		
HLT PT		

Cardiac disorders

Cardiac arrhythmias

Ventricular arrhythmias and cardiac arrest	Cardiac arrest	2	2
--	----------------	---	---

Heart failures

Heart failures NEC	Cardiac failure	2	2
--------------------	-----------------	---	---

Myocardial disorders

Noninfectious myocarditis	Myocarditis	2	2
---------------------------	-------------	---	---

Pericardial disorders

Pericardial disorders NEC	Pericardial effusion	2	2
---------------------------	----------------------	---	---

Cardiac disorders SOC Total

8

8

Gastrointestinal disorders

Gastrointestinal signs and symptoms

Nausea and vomiting symptoms	Nausea	2	2
------------------------------	--------	---	---

Gastrointestinal disorders SOC Total

2

2

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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM
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: 12
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

General disorders and administration site conditions

Fatal outcomes

Death and sudden death	Death	1	1
	Hanging	1	1

General system disorders NEC

General signs and symptoms NEC	Multiple organ dysfunction syndrome	2	2
Oedema NEC	Face oedema	2	2
	Oedema peripheral	2	2

Therapeutic and nontherapeutic effects (excl toxicity)

Therapeutic and nontherapeutic responses	Treatment noncompliance	2	2
--	-------------------------	---	---

General disorders and administration site conditions SOC 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
	Liver injury	2	2

Hepatobiliary disorders SOC Total

8 8

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Canada Vigilance Summary of Product Adverse Reactions

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	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

Poisoning and toxicity	Toxicity to various agents	3	3
------------------------	----------------------------	---	---

Injuries by physical agents

Thermal burns	Thermal burn	1	1
---------------	--------------	---	---

Overdoses and underdoses NEC

Overdoses NEC	Intentional overdose	2	2
	Overdose	2	2
Underdoses NEC	Underdose	1	1

Injury, poisoning and procedural complications SOC Total

9	9
---	---

Investigations

Metabolic, nutritional and blood gas investigations

Blood gas and acid base analyses	Oxygen saturation decreased	2	2
----------------------------------	-----------------------------	---	---

Investigations SOC Total

2	2
---	---

Musculoskeletal and connective tissue disorders

Muscle disorders

Muscle pains	Myalgia	2	2
--------------	---------	---	---

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).



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Canada Vigilance Summary of Product Adverse Reactions

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	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 and cerebrovascular accidents	Cerebrovascular accident	1	1
---	--------------------------	---	---

Encephalopathies

Encephalopathies NEC	Encephalopathy	2	2
Encephalopathies toxic and metabolic	Hepatic encephalopathy	2	2

Seizures (incl subtypes)

Seizures and seizure disorders NEC	Seizure	2	2
------------------------------------	---------	---	---

Nervous system disorders SOC Total

7	7
---	---

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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM
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: 12
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Psychiatric disorders

Anxiety disorders and symptoms

Anxiety symptoms	Agitation	2	2
------------------	-----------	---	---

Disturbances in thinking and perception

Delusional symptoms	Delusion of reference	1	1
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Personality disorders and disturbances in behaviour

Behaviour and socialisation disturbances	Aggression	1	1
--	------------	---	---

Schizophrenia and other psychotic disorders

Psychotic disorder NEC	Psychotic disorder	1	1
------------------------	--------------------	---	---

Sleep disorders and disturbances

Disturbances in initiating and maintaining sleep	Insomnia	1	1
--	----------	---	---

Suicidal and self-injurious behaviours NEC

Suicidal and self-injurious behaviour	Assisted suicide	1	1
	Completed suicide	11	11
	Suicidal ideation	1	1

Psychiatric disorders SOC Total

19 19

Respiratory, thoracic and mediastinal disorders

Pleural disorders

Pneumothorax and pleural effusions NEC	Pleural effusion	2	2
--	------------------	---	---

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).



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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: 12
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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Canada Vigilance Summary of Product Adverse Reactions

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

		2021															
		January		February		March		April		May		June		September		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	
Cardiac disorders	Cardiac arrest			1	1							1	1				
	Cardiac failure			1	1							1	1				
	Myocarditis			1	1							1	1				
	Pericardial effusion			1	1							1	1				
	SOC Subtotal			4	4							4	4				
Gastrointestinal disorders	Nausea			1	1							1	1				
	SOC Subtotal			1	1							1	1				



Canada Vigilance Summary of Product Adverse Reactions

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

			2021			
			November			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Cardiac disorders	Cardiac arrest				2	2
	Cardiac failure				2	2
	Myocarditis				2	2
	Pericardial effusion				2	2
	SOC Subtotal				8	8

Gastrointestinal disorders	Nausea				2	2
	SOC Subtotal				2	2



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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM
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: 12
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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l'information par Santé Canada

		2021														
		January		February		March		April		May		June		September		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
General disorders and administration site conditions	Death															
	Face oedema			1	1							1	1			
	Hanging					1	1									
	Multiple organ dysfunction syndrome			1	1							1	1			
	Oedema peripheral			1	1							1	1			
	Treatment noncompliance			1	1							1	1			
	SOC Subtotal			4	4	1	1					4	4			
Hepatobiliary disorders	Congestive hepatopathy			1	1							1	1			
	Hepatic failure			1	1							1	1			
	Hepatitis			1	1							1	1			
	Liver injury			1	1							1	1			
	SOC Subtotal			4	4							4	4			



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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM

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: 12

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

		2021				
		November				
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
General disorders and administration site conditions	Death		1	1	1	1
	Face oedema				2	2
	Hanging				1	1
	Multiple organ dysfunction syndrome				2	2
	Oedema peripheral				2	2
	Treatment noncompliance				2	2
	SOC Subtotal		1	1	10	10

Hepatobiliary disorders	Congestive hepatopathy				2	2
	Hepatic failure				2	2
	Hepatitis				2	2
	Liver injury				2	2
	SOC Subtotal				8	8



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM
 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: 12
 Age: All
 Gender: All
 MedDRA Version:
 Foreign or Domestic: Domestic

		2021														
		January		February		March		April		May		June		September		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
Injury, poisoning and procedural complications	Intentional overdose			1	1							1	1			
	Overdose			1	1							1	1			
	Thermal burn															
	Toxicity to various agents			1	1			1	1			1	1			
	Underdose															1
	SOC Subtotal			3	3			1	1			3	3			1
Investigations	Oxygen saturation decreased			1	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			



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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM

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: 12

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

			2021			
			November			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Injury, poisoning and procedural complications	Intentional overdose				2	2
	Overdose				2	2
	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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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM
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: 12
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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divulgué en vertu de la Loi sur l'accès à
l'information par Santé Canada

		2021														
		January		February		March		April		May		June		September		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
Nervous system disorders	Cerebrovascular accident					1	1									
	Encephalopathy			1	1							1	1			
	Hepatic encephalopathy			1	1							1	1			
	Seizure			1	1							1	1			
	SOC Subtotal			3	3	1	1					3	3			
Psychiatric disorders	Aggression	1	1													
	Agitation			1	1							1	1			
	Assisted suicide					1	1									
	Completed suicide	1	1	1	1	1	1	1	1	1	1	2	2	1	1	1
	Delusion of reference															
	Insomnia	1	1													
	Psychotic disorder	1	1													
	SOC Subtotal	5	5	2	2	2	2	1	1	1	1	3	3	1	1	1
Respiratory, thoracic and mediastinal disorders	Pleural effusion			1	1							1	1			
	SOC Subtotal			1	1							1	1			



Canada Vigilance Summary of Product Adverse Reactions

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

		2021			
		November			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions
Nervous system disorders	Cerebrovascular accident				1
	Encephalopathy				2
	Hepatic encephalopathy				2
	Seizure				2
	SOC Subtotal				7

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

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



Canada Vigilance Summary of Product Adverse Reactions

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

		2021															
		January		February		March		April		May		June		September		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	
	Grand Total	5	5	24	24	4	4	2	2	1	1	25	25	1	1	2	



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM
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: 12
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

		2021				
		November				
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
	Grand Total	2	5	5	69	69



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM

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: 12

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Cardiac disorders	Cardiac arrest	2	2	2	2
	Cardiac failure	2	2	2	2
	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
General disorders and administration site conditions	Death	1	1	1	1
	Face oedema	2	2	2	2
	Hanging	1	1	1	1
	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



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM

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: 12

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

		2021			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Hepatobiliary disorders	Congestive hepatopathy	2	2	2	2
	Hepatic failure	2	2	2	2
	Hepatitis	2	2	2	2
	Liver injury	2	2	2	2
	SOC Subtotal	8	8	8	8
Injury, poisoning and procedural complications	Intentional overdose	2	2	2	2
	Overdose	2	2	2	2
	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



Canada Vigilance Summary of Product Adverse Reactions

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

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



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-15 2:52 PM

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: 12

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

		2021			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Psychiatric disorders	Aggression	1	1	1	1
	Agitation	2	2	2	2
	Assisted suicide	1	1	1	1
	Completed suicide	11	11	11	11
	Delusion of reference	1	1	1	1
	Insomnia	1	1	1	1
	Psychotic disorder	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 / dexamethylphenidate, Metadate, Methylin, Ritalin, Vyvanse / Lisdexamfetamine, Dyanavel / Amphetamine Sulfate, Evekeo, Mydayis, Aptensio, Cotempla, Quillichew, Quillivant, Azstarys / serdexmethylphenidate and dexamethylphenidate".

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 [link](#) for additional caveats on the interpretation of suspected adverse reaction data collected by the Canada Vigilance program.



Canada Vigilance

Summary of Product Adverse Reactions

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 Occurrence	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 occurred. The age is unknown in some of the adverse reaction reports and age specific searches will not include reports where the age is unknown.
AR	Adverse Reaction
Gender	Gender of the patient as it was provided by the reporter. The gender is unknown in some of the adverse reaction reports and gender specific searches will not include reports where the gender is unknown.
Active Ingredient(s)	A health product includes drugs and natural health 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	The characterization of the role of the product as provided by the original reporter of the adverse reaction. The health product role reports the cause, opinion or observation of the individual reporter. Cause 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.
Health Product Role	
HLT	High Level Term – see definition of MedDRA
HLGT	High Level Group Term – see definition of MedDRA
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 annually. 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
Dosage Form	
Route of Administration	Preferred Term – A MedDRA-Preferred Term is an adverse reaction term which is a distinct descriptor (concept) for a symptom, sign, disease, diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical, social, or family history characteristic.
ATC	
ATC Pattern	The seriousness of the adverse reaction report is based on the following reasons: an adverse reaction 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 considered a medically important condition.
Reaction PTs	
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

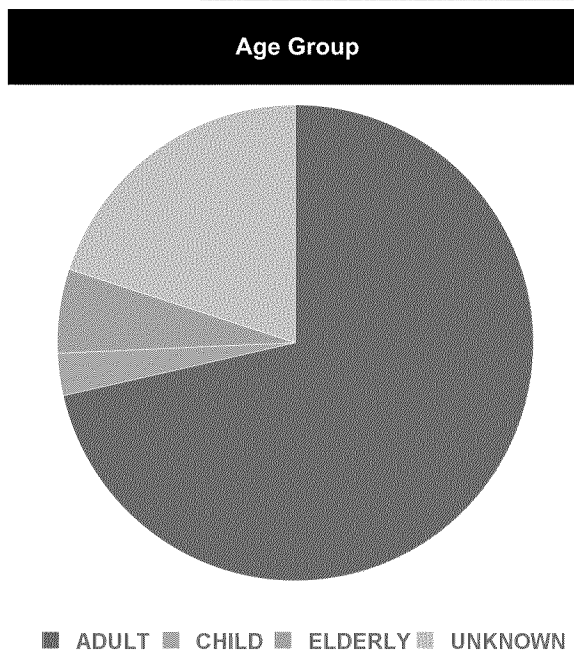
Report Runtime: 2022-02-16 9:29 AM
Health Product: See Search Criteria
Health Product Role:
Seriousness: All
Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 35
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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

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

Patient Sex		
Female	11	31.43%
Male	24	68.57%



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

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

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

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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

System Organ Class	Number of All Reactions*	Number of Reactions* where outcome of report was fatal
HLGT		
HLT PT		

Blood and lymphatic system disorders

Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Coagulopathies	Disseminated intravascular coagulation	1	1
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Platelet disorders

Thrombocytopenias	Thrombocytopenia	1	1
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White blood cell disorders

Leukocytoses NEC	Leukocytosis	1	1
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Blood and lymphatic 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).



Canada Vigilance Summary of Product Adverse Reactions

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

Cardiac disorders

Cardiac arrhythmias

Ventricular arrhythmias and cardiac arrest	Ventricular arrhythmia	2	2
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Cardiac valve disorders

Mitral valvular disorders	Mitral valve incompetence	1	1
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Heart failures

Heart failures NEC	Cardiac failure	1	1
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Myocardial disorders

Noninfectious myocarditis	Myocarditis	1	1
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Cardiac disorders SOC Total

5 5

Eye disorders

Ocular neuromuscular disorders

Ocular nerve and muscle disorders	Eye movement disorder	1	1
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Eye disorders SOC Total

1 1

Gastrointestinal disorders

Gastrointestinal signs and symptoms

Nausea and vomiting symptoms	Vomiting	1	1
------------------------------	----------	---	---

Gastrointestinal disorders SOC Total

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).



Canada Vigilance Summary of Product Adverse Reactions

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

General disorders and administration site conditions

Body temperature conditions

Febrile disorders	Pyrexia	1	1
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Fatal outcomes

Death and sudden death	Accidental death	4	4
	Death	3	3
	Sudden unexplained death in epilepsy	1	1

General system disorders NEC

Asthenic conditions	Malaise	2	2
General signs and symptoms NEC	Unmasking of previously unidentified disease	2	2
Pain and discomfort NEC	Chest pain	1	1

Therapeutic and nontherapeutic effects (excl toxicity)

Interactions	Drug interaction	18	18
	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

*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
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

Infections and infestations

Infections - pathogen unspecified

Cardiac infections	Endocarditis	1	1
Lower respiratory tract and lung infections	Pneumonia	3	3

Infections and infestations 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).



Canada Vigilance Summary of Product Adverse Reactions

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

Injury, poisoning and procedural complications

Exposures, chemical injuries and poisoning

Poisoning and toxicity	Toxicity to various agents	4	4
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Injuries NEC

Skin injuries NEC	Skin injury	1	1
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Medication errors and other product use errors 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 misuses/use issues

Intentional product use issues	Intentional product use issue	2	2
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Overdoses and underdoses NEC

Overdoses NEC	Intentional overdose	1	1
	Prescribed overdose	2	2

Injury, poisoning and procedural complications SOC Total

20 20

*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
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

Investigations

Cardiac and vascular investigations (excl enzyme tests)

ECG investigations	Electrocardiogram QT prolonged	2	2
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Enzyme investigations NEC

Skeletal and cardiac muscle analyses	Blood creatine phosphokinase increased	1	1
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Haematology investigations (incl blood groups)

Red blood cell analyses	Haemoglobin decreased	1	1
White blood cell analyses	Neutrophil count increased	1	1
	White blood cell count increased	1	1

Hepatobiliary investigations

Liver function analyses	Ammonia increased	1	1
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Toxicology and therapeutic drug monitoring

Therapeutic drug monitoring analyses	Antidepressant drug level above therapeutic	2	2
	Antipsychotic drug level increased	1	1
Toxicology laboratory analyses	Postmortem blood drug level	2	2

Investigations SOC Total

12 12

Nervous system disorders

Central nervous system vascular disorders

Central nervous system vascular disorders NEC	Cerebral amyloid angiopathy	2	2
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Increased intracranial pressure and hydrocephalus

Increased intracranial pressure disorders	Brain oedema	1	1
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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:29 AM
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Total Number of Reports: 35
Age: All
Gender: All
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Foreign or Domestic: Domestic

Mental impairment disorders			
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 NEC	Dyskinesia	2	2
	Tardive dyskinesia	2	2
Parkinson's disease and parkinsonism	Parkinsonism	2	2

Neurological disorders NEC			
Disturbances in consciousness NEC	Lethargy	1	1
	Somnolence	2	2
Neurological signs and symptoms NEC	Dizziness	6	6
	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 Total		33	33
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Canada Vigilance Summary of Product Adverse Reactions

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Health Product:	See Search Criteria	Age:	All
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Psychiatric disorders

Deliria (incl confusion)

Confusion and disorientation	Confusional state	4	4
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Depressed mood disorders and disturbances

Depressive disorders	Depression	16	16
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Disturbances in thinking and perception

Hallucinations (excl sleep-related)	Hallucination	2	2
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Psychiatric disorders NEC

Substance related and addictive disorders	Drug abuse	2	2
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Suicidal and self-injurious behaviours NEC

Suicidal and self-injurious behaviour	Suicide attempt	1	1
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Psychiatric disorders SOC Total

25	25
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Respiratory, thoracic and mediastinal disorders

Lower respiratory tract disorders (excl obstruction and infection)

Parenchymal lung disorders NEC	Atelectasis	1	1
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Pulmonary vascular disorders

Pulmonary thrombotic and embolic conditions	Pulmonary embolism	1	1
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Respiratory disorders NEC

Breathing abnormalities	Dyspnoea	2	2
	Respiratory depression	2	2
Respiratory failures (excl neonatal)	Respiratory failure	1	1

Respiratory tract signs and symptoms

Lower respiratory tract signs and symptoms	Rales	1	1
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Respiratory, thoracic and mediastinal disorders SOC Total

8 8

Skin and subcutaneous tissue disorders

Epidermal and dermal conditions

Bullous conditions	Stevens-Johnson syndrome	1	1
	Toxic epidermal necrolysis	1	1

Skin and subcutaneous tissue disorders SOC Total

2 2

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Social circumstances

Lifestyle issues

Disability issues	Loss of personal independence in daily activities	4	4
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Social circumstances SOC Total

4

4

Vascular disorders

Embolism and thrombosis

Peripheral embolism and thrombosis	Deep vein thrombosis	1	1
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Vascular disorders SOC Total

1

1

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		2021														
		February		March		April		May		June		July		August		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
Blood and lymphatic system disorders	Disseminated intravascular coagulation															
	Leukocytosis											1	1			
	Thrombocytopenia									1	1					
	SOC Subtotal									1	1	1	1			
Cardiac disorders	Cardiac failure											1	1			
	Mitral valve incompetence											1	1			
	Myocarditis											1	1			
	Ventricular arrhythmia													1	1	
	SOC Subtotal											3	3	1	1	
Eye disorders	Eye movement disorder									1	1					
	SOC Subtotal									1	1					
Gastrointestinal disorders	Vomiting									1	1					
	SOC Subtotal									1	1					
General disorders and administration site conditions	Accidental death							1	1					1	1	



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			2021							
			October		November		December			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Blood and lymphatic system disorders	Disseminated intravascular coagulation				1	1			1	1
	Leukocytosis								1	1
	Thrombocytopenia								1	1
	SOC Subtotal				1	1			3	3

Cardiac disorders	Cardiac failure								1	1
	Mitral valve incompetence								1	1
	Myocarditis								1	1
	Ventricular arrhythmia						1	1	2	2
	SOC Subtotal						1	1	5	5

Eye disorders	Eye movement disorder								1	1
	SOC Subtotal								1	1

Gastrointestinal disorders	Vomiting								1	1
	SOC Subtotal								1	1

General disorders and administration site conditions	Accidental death				1	1	1	1	4	4
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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
General disorders and administration site conditions	Chest pain											1	1			
	Death											1	1	1	1	
	Drug interaction	4	4			2	2	1	1	4	4			2	2	2
	Food interaction													1	1	
	Malaise													1	1	
	Multiple-drug resistance															
	Potentiating drug interaction													1	1	
	Pyrexia											1	1			
	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



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			October		November		December			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
General disorders and administration site conditions	Chest pain								1	1
	Death						1	1	3	3
	Drug interaction	2	1	1	1	1	1	1	18	18
	Food interaction						1	1	2	2
	Malaise						1	1	2	2
	Multiple-drug resistance				1	1			1	1
	Potentiating drug interaction						1	1	2	2
	Pyrexia								1	1
	Sudden unexplained death in epilepsy				1	1			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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Infections and infestations	Endocarditis											1	1			
	Pneumonia									1	1			1	1	
	SOC Subtotal									1	1	1	1	1	1	

Injury, poisoning and procedural complications	Failure to suspend medication							1	1							
	Incorrect route of product administration															
	Intentional overdose									1	1					
	Intentional product use issue							1	1							1
	Labelled drug-drug interaction issue													1	1	
	Prescribed overdose							1	1							1
	Product dose omission issue															
	Product use in unapproved indication															



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			2021							
			October		November		December			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Infections and infestations	Endocarditis								1	1
	Pneumonia						1	1	3	3
	SOC Subtotal						1	1	4	4

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



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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
Injury, poisoning and procedural complications	Skin injury															
	Toxicity to various agents			1	1			1	1			1	1			
	Wrong patient received product							1	1							
	SOC Subtotal			1	1			5	5	1	1	1	1	1	1	2



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SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal	
Injury, poisoning and procedural complications	Skin injury				1	1			1	1	
	Toxicity to various agents				1	1			4	4	
	Wrong patient received product				1	1			2	2	
	SOC Subtotal	2	3	3	5	5	1	1	20	20	



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Investigations	Ammonia increased									1	1					
	Antidepressant drug level above therapeutic													1	1	
	Antipsychotic drug level increased									1	1					
	Blood creatine phosphokinase increased									1	1					
	Electrocardiogram QT prolonged													1	1	
	Haemoglobin decreased									1	1					
	Neutrophil count increased											1	1			
	Postmortem blood drug level													1	1	
	White blood cell count increased											1	1			
	SOC Subtotal									4	4	2	2	3	3	

Nervous system disorders	Brain oedema									1	1					
	Cerebral amyloid angiopathy									1	1					
	Dementia Alzheimer's type									1	1					
	Dizziness			4	4											



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			October		November		December			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Investigations	Ammonia increased								1	1
	Antidepressant drug level above therapeutic						1	1	2	2
	Antipsychotic drug level increased								1	1
	Blood creatine phosphokinase increased								1	1
	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
	SOC Subtotal						3	3	12	12

Nervous system disorders	Brain oedema								1	1
	Cerebral amyloid angiopathy		1	1					2	2
	Dementia Alzheimer's type		1	1					2	2
	Dizziness				2	2			6	6



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Nervous system disorders	Dyskinesia									1	1					
	Generalised tonic-clonic seizure															
	Hypotonia									1	1					
	Lethargy															
	Mental impairment													1	1	
	Myelopathy									1	1					
	Parkinsonism									1	1					
	Somnolence													1	1	
	Status epilepticus															
	Tardive dyskinesia									1	1					
	Unresponsive to stimuli			4	4					1	1					
	SOC Subtotal			8	8					9	9			2	2	



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SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Nervous system disorders	Dyskinesia		1	1					2	2
	Generalised tonic-clonic seizure				1	1			1	1
	Hypotonia								1	1
	Lethargy		1	1					1	1
	Mental impairment						1	1	2	2
	Myelopathy								1	1
	Parkinsonism		1	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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Psychiatric disorders	Confusional state									1	1			1	1	
	Depression	4	4			2	2	1	1	4	4			1	1	2
	Drug abuse			1	1							1	1			
	Hallucination									1	1					
	Suicide attempt									1	1					
	SOC Subtotal	4	4	1	1	2	2	1	1	7	7	1	1	2	2	2
Respiratory, thoracic and mediastinal disorders	Atelectasis									1	1					
	Dyspnoea									1	1	1	1			
	Pulmonary embolism									1	1					
	Rales									1	1					
	Respiratory depression													1	1	
	Respiratory failure															
	SOC Subtotal									4	4	1	1	1	1	



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			October		November		December			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Psychiatric disorders	Confusional state		1	1			1	1	4	4
	Depression	2	1	1	1	1			16	16
	Drug abuse								2	2
	Hallucination		1	1					2	2
	Suicide attempt								1	1
	SOC Subtotal	2	3	3	1	1	1	1	25	25

Respiratory, thoracic and mediastinal disorders	Atelectasis								1	1
	Dyspnoea								2	2
	Pulmonary embolism								1	1
	Rales								1	1
	Respiratory depression						1	1	2	2
	Respiratory failure		1	1					1	1
	SOC Subtotal		1	1			1	1	8	8



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		February		March		April		May		June		July		August		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
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome															
	Toxic epidermal necrolysis															
	SOC Subtotal															
Social circumstances	Loss of personal independence in daily activities							1	1							1
	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



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			2021								
			October		November		December				
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 tissue disorders	Stevens-Johnson syndrome				1	1			1	1	
	Toxic epidermal necrolysis				1	1			1	1	
	SOC Subtotal				2	2			2	2	
Social circumstances	Loss of personal independence in daily activities	1	1	1	1	1			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	



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Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Blood and lymphatic system disorders	Disseminated intravascular coagulation	1	1	1	1
	Leukocytosis	1	1	1	1
	Thrombocytopenia	1	1	1	1
	SOC Subtotal	3	3	3	3
Cardiac disorders	Cardiac failure	1	1	1	1
	Mitral valve incompetence	1	1	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	1
	SOC Subtotal	1	1	1	1



Canada Vigilance Summary of Product Adverse Reactions

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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
General disorders and administration site conditions	Accidental death	4	4	4	4
	Chest pain	1	1	1	1
	Death	3	3	3	3
	Drug interaction	18	18	18	18
	Food interaction	2	2	2	2
	Malaise	2	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	1	1
	Unmasking of previously unidentified disease	2	2	2	2
SOC Subtotal		37	37	37	37



Canada Vigilance Summary of Product Adverse Reactions

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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Infections and infestations	Endocarditis	1	1	1	1
	Pneumonia	3	3	3	3
	SOC Subtotal	4	4	4	4



Canada Vigilance Summary of Product Adverse Reactions

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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Injury, poisoning and procedural complications	Failure to suspend medication	2	2	2	2
	Incorrect route of product administration	1	1	1	1
	Intentional overdose	1	1	1	1
	Intentional product use issue	2	2	2	2
	Labelled drug-drug interaction issue	2	2	2	2
	Prescribed overdose	2	2	2	2
	Product dose omission issue	1	1	1	1
	Product use in unapproved indication	2	2	2	2
	Skin injury	1	1	1	1
	Toxicity to various agents	4	4	4	4
	Wrong patient received product	2	2	2	2
SOC Subtotal		20	20	20	20



Canada Vigilance Summary of Product Adverse Reactions

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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Investigations	Ammonia increased	1	1	1	1
	Antidepressant drug level above therapeutic	2	2	2	2
	Antipsychotic drug level increased	1	1	1	1
	Blood creatine phosphokinase increased	1	1	1	1
	Electrocardiogram QT prolonged	2	2	2	2
	Haemoglobin decreased	1	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
Nervous system disorders	Brain oedema	1	1	1	1
	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



Canada Vigilance Summary of Product Adverse Reactions

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

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



Canada Vigilance Summary of Product Adverse Reactions

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



Canada Vigilance Summary of Product Adverse Reactions

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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Respiratory, thoracic and mediastinal disorders	Atelectasis	1	1	1	1
	Dyspnoea	2	2	2	2
	Pulmonary embolism	1	1	1	1
	Rales	1	1	1	1
	Respiratory depression	2	2	2	2
	Respiratory failure	1	1	1	1
	SOC Subtotal	8	8	8	8
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	1	1	1	1
	Toxic epidermal necrolysis	1	1	1	1
	SOC Subtotal	2	2	2	2



Canada Vigilance Summary of Product Adverse Reactions

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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	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
	Grand Total	156	156	156	156



Canada Vigilance

Summary of Product Adverse Reactions

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 Occurrence	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	Age of the patient when the adverse reaction occurred. Some adverse reaction reports and age specific search terms include reports where the age is unknown.	amphetamine aspartate monohydrate amphetamine sulfate methylenedioxyamphetamine amphetamine aspartate 2,5-DIMETHOXY-4-METHYLAMPHETAMINE
AR	Adverse Reaction	AMPHETAMINE methamphetamine methamphetamine hydrochloride METHYLENEDIOXYMETHAMPHETAMINE
Gender	Gender of the patient as it was provided by the reporter. The gender is unknown in some of the adverse reaction reports and gender specific search terms will not include reports where the gender is unknown.	METHYLENEDIOXYAMPHETAMINE AMPHETAMINE SULFATE PARA-METHOXYMETHAMPHETAMINE mixed salts amphetamine METHAMPHETAMINE SACCHARATE amphetamine
Health Product	A health product includes drugs and natural health 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.	dexamphetamine sulphate Methylenedioxymethamphetamine 3,4-methylenedioxy-N-methylamphetamine
Health Product Role	The characterization of the role of the health product as provided by the original reporter of the adverse reaction. The health product role represents the suspected or observation of the individual reporter. Cause and effect relationship indicates that 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.	methamphetamine METHAMPHETAMINE DEXMETHYLPHENIDATE HYDROCHLORIDE
HLT	High Level Term – see definition of MedDRA	METHYLPHENIDATE methamphetamine METHYLPHENIDATE HYDROCHLORIDE
HLGT	High Level Group Term – see definition of MedDRA	METHYLPHENIDATE DEXMETHYLPHENIDATE HYDROCHLORIDE
Initial Date of Receipt	The date that the first version of the adverse reaction report was received by Health Canada's Canada Vigilance Program.	DEXMETHYLPHENIDATE HYDROCHLORIDE METHYLPHENIDATE methamphetamine METHYLPHENIDATE HYDROCHLORIDE
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.	DEXMETHYLPHENIDATE DEXMETHYLPHENIDATE HYDROCHLORIDE METHYLPHENIDATE METHYLPHENIDATE HYDROCHLORIDE LISDEXAMFETAMINE Lisdexamfetamine Lisdexamfetamine Lisdexamfetamine Mesilate Lisdexamfetamine dimesylate LISDEXAMFETAMINE DIMESYLATE
MedDRA Version	The MedDRA terminology is updated on a biennial scheduled basis. The MedDRA version displayed reflects the version in use at the time of producing the summary.	LISDEXAMFETAMINE DIMESYLATE LISDEXAMFETAMINE MESILATE LISDEXAMFETAMINE DIMESYLATE LISDEXAMFETAMINE DIMESYLATE
NEC	Not Elsewhere Classified – MedDRA abbreviation	LISDEXAMFETAMINE DIMESYLATE
NOS	Not Otherwise Specified – MedDRA abbreviation	LISDEXAMFETAMINE DIMESYLATE
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.	LISDEXAMFETAMINE DIMESYLATE
Seriousness	The seriousness of the adverse reaction is determined by the following reasons: an adverse reaction that required in-patient hospitalization or medical attention; a congenital abnormality, 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.	LISDEXAMFETAMINE DIMESYLATE
SOC	System Organ Class – A System Organ Class is the highest level of the hierarchy that provides the broadest concept for data retrieval.	LISDEXAMFETAMINE DIMESYLATE
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

Report Runtime: 2022-02-16 9:59 AM
Health Product: See Search Criteria
Health Product Role:
Seriousness: All
Initial Date of Receipt: 2021-01-01 to 2021-12-31

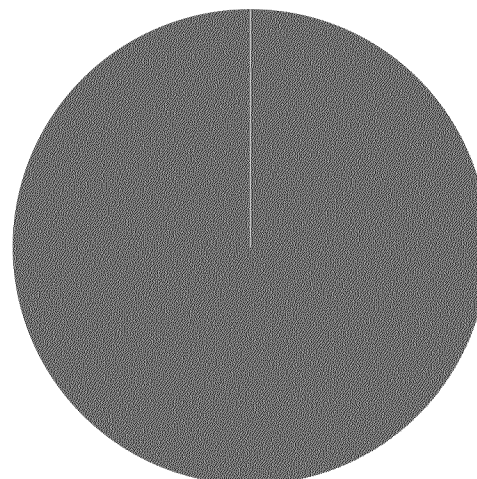
Total Number of Reports: 32
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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

Age Group		
ADULT	32	100.00%

Age Group		
-----------	--	--

Patient Sex		
Female	10	31.25%
Male	22	68.75%



■ 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

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Total Number of Reports: 32
Age: All
Gender: All
MedDRA Version:
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

Report Runtime: 2022-02-16 9:59 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: 32
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

System Organ Class	Number of All Reactions*	Number of Reactions* where outcome of report was fatal
HLGT		
HLT PT		

Cardiac disorders

Cardiac arrhythmias

Ventricular arrhythmias and cardiac arrest	Cardiac arrest	2	2
	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
--------------------------	------------------------------	---	---

Cardiac disorders SOC Total

11

11

Gastrointestinal disorders

Gastrointestinal vascular conditions

Gastrointestinal vascular occlusion and infarction	Intestinal infarction	2	2
--	-----------------------	---	---

Gastrointestinal disorders SOC Total

2

2

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Canada Vigilance Summary of Product Adverse Reactions

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

General disorders and administration site conditions

Fatal outcomes

Death and sudden death	Death	5	5
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General disorders and administration site conditions SOC Total

5	5
---	---

Hepatobiliary disorders

Hepatic and hepatobiliary disorders

Hepatocellular damage and hepatitis NEC	Hepatic necrosis	2	2
--	------------------	---	---

Hepatobiliary disorders SOC Total

2	2
---	---

Infections and infestations

Infections - pathogen unspecified

Lower respiratory tract and lung infections	Pneumonia aspiration	1	1
	Pneumonia necrotising	1	1

Infections and infestations SOC Total

2	2
---	---

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Canada Vigilance Summary of Product Adverse Reactions

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

Injury, poisoning and procedural complications

Exposures, chemical injuries and poisoning

Poisoning and toxicity	Poisoning	3	3
	Toxicity to various agents	19	19

Injuries NEC

Non-site specific injuries NEC	Fall	1	1
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Medication errors and other product use errors and issues

Medication errors, product use errors and issues NEC	Product use in unapproved indication	1	1
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Overdoses and underdoses NEC

Overdoses NEC	Overdose	5	5
---------------	----------	---	---

Injury, poisoning and procedural complications SOC Total

29	29
----	----

*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
 Health Product: See Search Criteria
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 Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 32
 Age: All
 Gender: All
 MedDRA Version:
 Foreign or Domestic: Domestic

Investigations**Toxicology and therapeutic drug monitoring**

Toxicology laboratory analyses	Amphetamines positive	10	10
	Antemortem blood drug level increased	1	1
	Blood ethanol	1	1
	Blood ethanol increased	3	3
	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
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Neurological disorders NEC

Disturbances in consciousness NEC	Depressed level of consciousness	1	1
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Seizures (incl subtypes)

Seizures and seizure disorders NEC	Seizure	1	1
	Status epilepticus	2	2

Nervous system disorders SOC Total**6****6**

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Canada Vigilance Summary of Product Adverse Reactions

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Total Number of Reports: 32
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Psychiatric disorders

Psychiatric disorders NEC

Substance related and addictive disorders	Drug abuse	14	14
---	------------	----	----

Psychiatric disorders SOC Total

14 14

Renal and urinary disorders

Renal disorders (excl nephropathies)

Renal vascular and ischaemic conditions	Renal infarct	2	2
---	---------------	---	---

Renal and urinary disorders SOC Total

2 2

Respiratory, thoracic and mediastinal disorders

Bronchial disorders (excl neoplasms)

Bronchospasm and obstruction	Chronic obstructive pulmonary disease	1	1
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Lower respiratory tract disorders (excl obstruction and infection)

Lower respiratory tract inflammatory and immunologic conditions	Pneumonitis	2	2
---	-------------	---	---

Respiratory, thoracic and mediastinal 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).



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Total Number of Reports: 32
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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l'information par Santé Canada

		2021														
		January		February		March		April		May		June		July		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
Cardiac disorders	Cardiac arrest															
	Cardiogenic shock							1	1							
	Cardio-respiratory arrest															
	Cor pulmonale							1	1							
	Left ventricular dysfunction															
	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	1	1	2	2							1	1			1
	SOC Subtotal	1	1	2	2							1	1			1
Hepatobiliary disorders	Hepatic necrosis					1	1							1	1	
	SOC Subtotal					1	1							1	1	



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Total Number of Reports: 32
 Age: All
 Gender: All
 MedDRA Version:
 Foreign or Domestic: Domestic

			2021							
			October		November		December			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Cardiac disorders	Cardiac arrest		1	1			1	1	2	2
	Cardiogenic shock								1	1
	Cardio-respiratory arrest		4	4	1	1			5	5
	Cor pulmonale								1	1
	Left ventricular dysfunction		1	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	1							5	5
	SOC Subtotal	1							5	5
Hepatobiliary disorders	Hepatic necrosis								2	2
	SOC Subtotal								2	2



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Report Runtime: 2022-02-16 9:59 AM
 Health Product: See Search Criteria
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 Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 32
 Age: All
 Gender: All
 MedDRA Version:
 Foreign or Domestic: Domestic

		2021															
		January		February		March		April		May		June		July		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	
Infections and infestations	Pneumonia aspiration											1	1				
	Pneumonia necrotising											1	1				
	SOC Subtotal											2	2				

Injury, poisoning and procedural complications	Fall					1	1										
	Overdose																
	Poisoning																
	Product use in unapproved indication																
	Toxicity to various agents					4	4	1	1	2	2	3	3	2	2		
	SOC Subtotal					5	5	1	1	2	2	3	3	2	2		



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Canada Vigilance Summary of Product Adverse Reactions

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 Age: All
 Gender: All
 MedDRA Version:
 Foreign or Domestic: Domestic

			2021							
			October		November		December			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Infections and infestations	Pneumonia aspiration								1	1
	Pneumonia necrotising								1	1
	SOC Subtotal								2	2

Injury, poisoning and procedural complications	Fall								1	1
	Overdose		4	4	1	1			5	5
	Poisoning		1	1	2	2			3	3
	Product use in unapproved indication				1	1			1	1
	Toxicity to various agents		5	5	2	2			19	19
SOC Subtotal			10	10	6	6			29	29



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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:59 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: 32
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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l'information par Santé Canada

		2021														
		January		February		March		April		May		June		July		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
Investigations	Amphetamines positive					3	3			1	1	4	4			
	Antemortem blood drug level increased					1	1									
	Blood ethanol					1	1									
	Blood ethanol increased											2	2			
	Opiates positive					4	4					3	3			
	Postmortem blood drug level					2	2			1	1	1	1			
	Postmortem blood drug level abnormal											2	2			
	Postmortem blood drug level increased					2	2	1	1	1	1					
	SOC Subtotal					13	13	1	1	3	3	12	12			
Nervous system disorders	Depressed level of consciousness											1	1			
	Hypoxic-ischaemic encephalopathy															
	Seizure									1	1					
	Status epilepticus															
	SOC Subtotal									1	1	1	1			



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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:59 AM
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 Seriousness: All
 Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 32
 Age: All
 Gender: All
 MedDRA Version:
 Foreign or Domestic: Domestic

		2021								
		October			November		December			
SOC	PT	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Investigations	Amphetamines positive		2	2					10	10
	Antemortem blood drug level increased								1	1
	Blood ethanol								1	1
	Blood ethanol increased		1	1					3	3
	Opiates positive		2	2					9	9
	Postmortem blood drug level		1	1					5	5
	Postmortem blood drug level abnormal		1	1					3	3
	Postmortem blood drug level increased								4	4
	SOC Subtotal		7	7					36	36

Nervous system disorders	Depressed level of consciousness								1	1
	Hypoxic-ischaemic encephalopathy		1	1			1	1	2	2
	Seizure								1	1
	Status epilepticus		1	1			1	1	2	2
	SOC Subtotal		2	2			2	2	6	6



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:59 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: 32
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

		2021														
		January		February		March		April		May		June		July		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
Psychiatric disorders	Drug abuse											3	3			
	SOC Subtotal											3	3			
Renal and urinary disorders	Renal infarct					1	1							1	1	
	SOC Subtotal					1	1							1	1	
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease							1	1							
	Pneumonitis															
	SOC Subtotal							1	1							
	Grand Total	1	1	2	2	21	21	5	5	6	6	22	22	5	5	1



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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:59 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: 32

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

			2021								
			October		November		December				
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 and mediastinal disorders	Chronic obstructive pulmonary disease								1	1	
	Pneumonitis		1	1			1	1	2	2	
	SOC Subtotal		1	1			1	1	3	3	
	Grand Total	1	33	33	11	11	5	5	112	112	



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:59 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: 32

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Cardiac disorders	Cardiac arrest	2	2	2	2
	Cardiogenic shock	1	1	1	1
	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 infestations	Pneumonia aspiration	1	1	1	1
	Pneumonia necrotising	1	1	1	1
	SOC Subtotal	2	2	2	2



Canada Vigilance Summary of Product Adverse Reactions

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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Injury, poisoning and procedural complications	Fall	1	1	1	1
	Overdose	5	5	5	5
	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



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 9:59 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: 32

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Investigations	Amphetamines positive	10	10	10	10
	Antemortem blood drug level increased	1	1	1	1
	Blood ethanol	1	1	1	1
	Blood ethanol increased	3	3	3	3
	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	4
	SOC Subtotal	36	36	36	36
Nervous system disorders	Depressed level of consciousness	1	1	1	1
	Hypoxic-ischaemic encephalopathy	2	2	2	2
	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



Canada Vigilance Summary of Product Adverse Reactions

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

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Renal and urinary disorders	Renal infarct	2	2	2	2
	SOC Subtotal	2	2	2	2
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	1	1	1	1
	Pneumonitis	2	2	2	2
	SOC Subtotal	3	3	3	3
	Grand Total	112	112	112	112

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, Lorazepam / 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 [link](#) for additional caveats on the interpretation of suspected adverse reaction data collected by the Canada Vigilance program.



Canada Vigilance

Summary of Product Adverse Reactions

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 Occurrence	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, CLIDINIUM CHLORDIAZEPOXIDE? CLIDINIUM BROMIDE? DICLOFENAC chlordiazepoxide hydrochloride CHLORDIAZEPOXIDE HYDROCHLORIDE CHLORDIAZEPOXIDE Chlordiazepoxide Hydrochloride Chlordiazepoxide CHLORDIAZEPOXIDE? CLIDINIUM CHLORDIAZEPOXIDE HYDROCHLORIDE? CLIDINIUM 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

Term	Definition
Age	Age of the patient when the adverse reaction occurred. The age is unknown in some of the adverse reaction reports and age specific searches will not include reports where the age is unknown.
AR	Adverse Reaction CLORAZEPATE DIPOTASSIUM CLORAZEPATE DIPOTASSIQUE
Gender	Gender of the patient as it was provided by the reporter. The gender is unknown in some of the adverse reaction reports and gender specific searches will not include reports where the gender is unknown.
Health Product	A health product includes drugs and natural health 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. Diazepam DIAZEPAM Nordiazeepam
Health Product Role	The characterization of the role of the product as provided by the original reporter of the adverse reaction. The health product role represents the suspected role of the individual reporter. Cause 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. Nordiazeepam DIAZEPAM? PARACETAMOL CHLORDESMETHYL DIAZEPAM NORDIAZEPAM Diazepam DIAZEPAM chlordesmethyldiazepam DIAZEPAM? SULPIRIDE
HLT	High Level Term – see definition of MedDRA DIAZEPAM? DICYCLOVERINE
HLGT	High Level Group Term – see definition of MedDRA FLUDIAZEPAM nalazeepam
Initial Date of Receipt	The date that the first version of the adverse reaction report was received by Health Canada's Canada Vigilance Program. HALAZEPAM Lorazepam lorazepam 3-o-phenolic glucuronide (pk ana)
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. Lorazepam LORAZEPAM? TEMAZEPAM LORAZEPAM chlorazepam DELORAZEPAM Delorazepam CHLORAZEPAM
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 processing the summary.
NEC	Not Elsewhere Classified – MedDRA abbreviation OXAZEPAM
NOS	Not Otherwise Specified – MedDRA abbreviation OXAZEPAM SUCCINATE
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. Oxazepam prazepam PRAZEPAM flutoprazepam
Seriousness	The seriousness of the adverse reaction is based on the following reasons: an adverse reaction that required in-patient hospitalization or a prolonged 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. Brazepam CLONAZEPAM quazepam QUAZEPAM
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. clonazepam CLONAZEPAM CLONAZEPAMUM CLONAZEPAM
Dosage Form	All
Route of Administration	All



Route of Administration	All
ATC	All
ATC Pattern	All
Reaction PTs	All



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Canada Vigilance Summary of Product Adverse Reactions

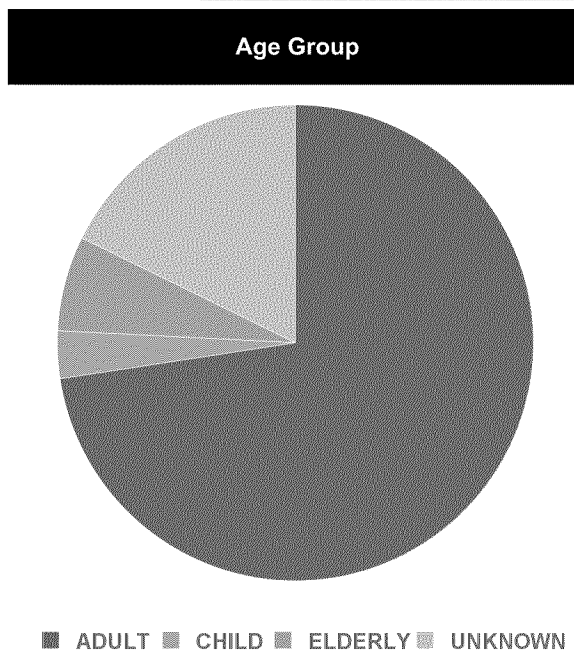
Report Runtime: 2022-02-16 11:23 AM
Health Product: See Search Criteria
Health Product Role:
Seriousness: All
Initial Date of Receipt: 2021-01-01 to 2021-12-31

Total Number of Reports: 62
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousness	
208	62	62	Death	62
			Life Threatening	11
			Hospitalization required	15
			Disability	0
			Congenital Anomaly	0
			Other Medically Important Condition	42

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

Patient Sex		
Female	22	35.48%
Male	40	64.52%



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

Report Runtime: 2022-02-16 11:23 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: 62
Age: All
Gender: All
MedDRA Version:
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).



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:23 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: 62
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

System Organ Class	Number of All Reactions*	Number of Reactions* where outcome of report was fatal
HLGT		
HLT PT		

Blood and lymphatic system disorders

Anaemias nonhaemolytic and marrow depression

Anaemias NEC	Anaemia	1	1
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Platelet disorders

Thrombocytopenias	Thrombocytopenia	1	1
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White blood cell disorders

Leukocytoses NEC	Leukocytosis	1	1
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Blood and lymphatic system disorders SOC Total

3 3

Cardiac disorders

Cardiac arrhythmias

Rate and rhythm disorders NEC	Arrhythmia	1	1
	Bradycardia	1	1
Ventricular arrhythmias and cardiac arrest	Cardiac arrest	1	1
	Cardio-respiratory arrest	5	5
	Pulseless electrical activity	1	1

Cardiac disorders SOC Total

9 9

*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 11:23 AM
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Total Number of Reports: 62
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Gastrointestinal disorders

Gastrointestinal vascular conditions

Gastrointestinal vascular occlusion and infarction	Intestinal infarction	2	2
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Peritoneal and retroperitoneal conditions

Peritoneal and retroperitoneal disorders	Ascites	2	2
--	---------	---	---

Gastrointestinal disorders SOC Total

4 4

General disorders and administration site conditions

Fatal outcomes

Death and sudden death	Accidental death	3	3
	Death	6	6

General system disorders NEC

Asthenic conditions	Fatigue	2	2
	Malaise	1	1
General signs and symptoms NEC	Disease progression	1	1
	Multiple organ dysfunction syndrome	1	1
Oedema NEC	Oedema	1	1

Therapeutic and nontherapeutic effects (excl toxicity)

Interactions	Drug interaction	16	16
Withdrawal and rebound effects	Drug withdrawal syndrome	1	1

General disorders and administration site conditions SOC Total

32 32

*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 11:23 AM
Health Product: See Search Criteria
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Total Number of Reports: 62
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Hepatobiliary disorders

Hepatic and hepatobiliary disorders			
Hepatic fibrosis and cirrhosis	Hepatic cirrhosis	2	2
Hepatocellular damage and hepatitis NEC	Hepatic necrosis	2	2
Hepatobiliary disorders SOC Total		4	4

Immune system disorders

Allergic conditions			
Allergies to foods, food additives, drugs and other chemicals	Reaction to excipient	1	1
Immune system disorders SOC Total		1	1

Injury, poisoning and procedural complications

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

Exposures, chemical injuries and poisoning			
Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	1	1
Poisoning and toxicity	Poisoning	3	3
	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).



Canada Vigilance Summary of Product Adverse Reactions

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

Non-site specific injuries NEC	Road traffic accident	1	1
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Medication errors and other product use errors and issues			
Medication errors, product use errors and issues NEC	Product use in unapproved indication	3	3
Product administration errors and issues	Failure to suspend medication	2	2
	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

Off label uses and intentional product misuses/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			
Overdoses NEC	Overdose	15	15
	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).



Canada Vigilance Summary of Product Adverse Reactions

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

Investigations

Toxicology and therapeutic drug monitoring			
Therapeutic drug monitoring analyses	Analgesic drug level	1	1
	Antasthmatic drug level	1	1
	Benzodiazepine drug level therapeutic	1	1
Toxicology laboratory analyses	Blood ethanol increased	1	1
	Opiates positive	2	2
	Postmortem blood drug level abnormal	1	1
	Postmortem blood drug level increased	1	1
Investigations SOC Total		8	8

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Metastases			
Metastases to specified sites	Metastases to liver	1	1
	Metastases to spine	1	1
Nervous system neoplasms malignant and unspecified NEC			
Central nervous system neoplasms malignant NEC	Malignant cranial nerve neoplasm	1	1
Nervous system neoplasms malignant NEC	Neuroblastoma recurrent	1	1
Ocular neoplasms			
Ocular neoplasms malignancy unspecified	Retro-orbital neoplasm	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps) SOC Total		5	5

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Nervous system disorders

Central nervous system vascular disorders

Central nervous system haemorrhages and cerebrovascular accidents	Haemorrhage intracranial	1	1
	Ischaemic cerebral infarction	2	2

Increased intracranial pressure and hydrocephalus

Increased intracranial pressure disorders	Brain oedema	2	2
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Neurological disorders NEC

Disturbances in consciousness NEC	Lethargy	1	1
	Loss of consciousness	3	3
	Somnolence	1	1
Neurological signs and symptoms NEC	Dizziness	8	8
	Unresponsive to stimuli	7	7

Neuromuscular disorders

Muscle tone abnormal	Serotonin syndrome	2	2
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Peripheral neuropathies

Mononeuropathies	Nerve compression	1	1
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Structural brain disorders

Structural brain disorders NEC	Brain injury	1	1
--------------------------------	--------------	---	---

Nervous system disorders SOC Total

29 29

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Pregnancy, puerperium and perinatal conditions

Abortions and stillbirth

Stillbirth and foetal death	Foetal death	2	2
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Pregnancy, puerperium and perinatal conditions SOC Total

2 2

Psychiatric disorders

Anxiety disorders and symptoms

Anxiety symptoms	Anxiety	1	1
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Depressed mood disorders and disturbances

Depressive disorders	Depression	16	16
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Mood disorders and disturbances NEC

Emotional and mood disturbances NEC	Irritability	1	1
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Psychiatric disorders NEC

Mental disorders NEC	Mental disorder	2	2
Substance related and addictive disorders	Drug abuse	10	10
	Drug dependence	3	3

Sleep disorders and disturbances

Disturbances in initiating and maintaining sleep	Insomnia	1	1
Sleep disorders NEC	Sleep disorder	1	1

Psychiatric disorders SOC Total

35 35

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Renal and urinary disorders

Renal disorders (excl nephropathies)

Renal vascular and ischaemic conditions	Renal infarct	2	2
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Renal and urinary disorders SOC Total

2

2

Respiratory, thoracic and mediastinal disorders

Lower respiratory tract disorders (excl obstruction and infection)

Pulmonary oedemas	Pulmonary congestion	1	1
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Respiratory disorders NEC

Respiratory failures (excl neonatal)	Respiratory failure	1	1
--------------------------------------	---------------------	---	---

Respiratory, thoracic and mediastinal disorders SOC Total

2

2

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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Seriousness:	All	MedDRA Version:	
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Vascular disorders

Decreased and nonspecific blood pressure disorders and shock

Vascular hypotensive disorders	Hypotension	1	1
	Orthostatic hypotension	1	1

Vascular disorders NEC

Site specific vascular disorders NEC	Pallor	1	1
--------------------------------------	--------	---	---

Vascular disorders SOC Total

3	3
---	---

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		January		February		March		April		May		June		July		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 and lymphatic system disorders	Anaemia			1	1											
	Leukocytosis			1	1											
	Thrombocytopenia			1	1											
	SOC Subtotal			3	3											
Cardiac disorders	Arrhythmia															
	Bradycardia									1	1					
	Cardiac arrest									1	1					
	Cardio-respiratory arrest															
	Pulseless electrical activity									1	1					
	SOC Subtotal									3	3					
Gastrointestinal disorders	Ascites							1	1							
	Intestinal infarction					1	1							1	1	
	SOC Subtotal					1	1	1	1					1	1	



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		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
Blood and lymphatic system disorders	Anaemia										1	1
	Leukocytosis										1	1
	Thrombocytopenia										1	1
	SOC Subtotal										3	3

Cardiac disorders	Arrhythmia						1	1			1	1
	Bradycardia										1	1
	Cardiac arrest										1	1
	Cardio-respiratory arrest				4	4	1	1			5	5
	Pulseless electrical activity										1	1
	SOC Subtotal				4	4	2	2			9	9

Gastrointestinal disorders	Ascites								1	1	2	2
	Intestinal infarction										2	2
	SOC Subtotal								1	1	4	4



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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
General disorders and administration site conditions	Accidental death									1	1					
	Death	1	1									1	1	2	2	
	Disease progression									1	1					
	Drug interaction			4	4			2	2	1	1	4	4			1
	Drug withdrawal syndrome											1	1			
	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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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
General disorders and administration site conditions	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
	Drug withdrawal syndrome										1	1
	Fatigue						1	1			2	2
	Malaise						1	1			1	1
	Multiple organ dysfunction syndrome								1	1	1	1
	Oedema						1	1			1	1
SOC Subtotal		1	2	2	1	1	7	7	2	2	32	32



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Hepatobiliary disorders	Hepatic cirrhosis							1	1							
	Hepatic necrosis					1	1							1	1	
	SOC Subtotal					1	1	1	1					1	1	
Immune system disorders	Reaction to excipient					1	1									
	SOC Subtotal					1	1									
Injury, poisoning and procedural complications	Abdominal injury															
	Brain herniation							1	1							
	Exposure during pregnancy															
	Failure to suspend medication									1	1					
	Fall															
	Hip fracture															
	Incorrect route of product administration															



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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
Hepatobiliary disorders	Hepatic cirrhosis								1	1	2	2
	Hepatic necrosis										2	2
	SOC Subtotal								1	1	4	4

Immune system disorders	Reaction to excipient										1	1
	SOC Subtotal										1	1

Injury, poisoning and procedural complications	Abdominal injury						1	1			1	1
	Brain herniation								1	1	2	2
	Exposure during pregnancy		1	1							1	1
	Failure to suspend medication						1	1			2	2
	Fall		1	1			1	1			2	2
	Hip fracture		1	1							1	1
	Incorrect route of product administration				1	1					1	1



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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
Injury, poisoning and procedural complications	Intentional product misuse															
	Intentional product use issue									1	1					
	Labelled drug-drug interaction issue															
	Off label use			1	1			1	1							
	Overdose									1	1					
	Pelvic fracture															
	Poisoning															
	Prescribed overdose									1	1					
	Product use in unapproved indication															
	Road traffic accident															



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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
Injury, poisoning and procedural complications	Intentional product misuse						1	1			1	1
	Intentional product use issue		1	1							2	2
	Labelled drug-drug interaction issue						1	1			1	1
	Off label use								1	1	3	3
	Overdose				7	7	3	3	4	4	15	15
	Pelvic fracture						1	1			1	1
	Poisoning				1	1	2	2			3	3
	Prescribed overdose		1	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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		2021														
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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
Injury, poisoning and procedural complications	Toxicity to various agents					2	2			1	1	1	1	1	1	
	Wrist fracture															
	Wrong patient received product									1	1					
	SOC Subtotal			1	1	2	2	2	2	6	6	1	1	1	1	
Investigations	Analgesic drug level					1	1									
	Antasthmatic drug level					1	1									
	Benzodiazepine drug level therapeutic											1	1			
	Blood ethanol increased											1	1			
	Opiates positive					1	1					1	1			
	Postmortem blood drug level abnormal					1	1									
	Postmortem blood drug level increased											1	1			
	SOC Subtotal					4	4					4	4			



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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
Injury, poisoning and procedural complications	Toxicity to various agents				7	7	5	5	3	3	20	20
	Wrist fracture		1	1							1	1
	Wrong patient received product						1	1			2	2
SOC Subtotal			6	6	18	18	19	19	9	9	65	65

Investigations	Analgesic drug level										1	1
	Antasthmatic drug level										1	1
	Benzodiazepine drug level therapeutic										1	1
	Blood ethanol increased										1	1
	Opiates positive										2	2
	Postmortem blood drug level abnormal										1	1
	Postmortem blood drug level increased										1	1
SOC Subtotal											8	8



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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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant cranial nerve neoplasm			1	1											
	Metastases to liver			1	1											
	Metastases to spine			1	1											
	Neuroblastoma recurrent			1	1											
	Retro-orbital neoplasm			1	1											
	SOC Subtotal			5	5											



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		2021										
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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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant cranial nerve neoplasm										1	1
	Metastases to liver										1	1
	Metastases to spine										1	1
	Neuroblastoma recurrent										1	1
	Retro-orbital neoplasm										1	1
SOC Subtotal											5	5



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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
Nervous system disorders	Brain injury									1	1					
	Brain oedema							1	1							
	Dizziness					4	4									
	Haemorrhage intracranial															
	Ischaemic cerebral infarction							1	1							
	Lethargy															
	Loss of consciousness									1	1	1	1			
	Nerve compression			1	1											
	Serotonin syndrome							1	1							
	Somnolence															
	Unresponsive to stimuli					4	4									
	SOC Subtotal			1	1	8	8	3	3	2	2	1	1			



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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	Brain injury										1	1
	Brain oedema								1	1	2	2
	Dizziness		1	1			3	3			8	8
	Haemorrhage intracranial		1	1							1	1
	Ischaemic cerebral infarction								1	1	2	2
	Lethargy				1	1					1	1
	Loss of consciousness								1	1	3	3
	Nerve compression										1	1
	Serotonin syndrome								1	1	2	2
	Somnolence						1	1			1	1
	Unresponsive to stimuli						2	2	1	1	7	7
SOC Subtotal			2	2	1	1	6	6	5	5	29	29



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		2021														
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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															

Psychiatric disorders	Anxiety															
	Depression			4	4			2	2	1	1	4	4			1
	Drug abuse															
	Drug dependence															
	Insomnia															
	Irritability											1	1			
	Mental disorder							1	1							
	Sleep disorder											1	1			
	SOC Subtotal			4	4			3	3	1	1	6	6			1

Renal and urinary disorders	Renal infarct					1	1							1	1	
	SOC Subtotal					1	1							1	1	



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			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
Pregnancy, puerperium and perinatal conditions	Foetal death		2	2							2	2
	SOC Subtotal		2	2							2	2
Psychiatric disorders	Anxiety						1	1			1	1
	Depression	1	2	2	1	1	1	1			16	16
	Drug abuse				5	5	4	4	1	1	10	10
	Drug dependence						1	1	2	2	3	3
	Insomnia						1	1			1	1
	Irritability										1	1
	Mental disorder						1	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										2	2
	SOC Subtotal										2	2



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 Age: All
 Gender: All
 MedDRA Version:
 Foreign or Domestic: Domestic

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 l'information par Santé Canada

		2021														
		January		February		March		April		May		June		July		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
Respiratory, thoracic and mediastinal disorders	Pulmonary congestion															
	Respiratory failure															
	SOC Subtotal															
Social circumstances	Loss of personal independence in daily activities									1	1					
	SOC Subtotal									1	1					
Vascular disorders	Hypotension									1	1					
	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



Canada Vigilance Summary of Product Adverse Reactions

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

		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
Respiratory, thoracic and mediastinal disorders	Pulmonary congestion						1	1			1	1
	Respiratory failure				1	1					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
Vascular disorders	Hypotension										1	1
	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



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:23 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: 62
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Blood and lymphatic system disorders	Anaemia	1	1	1	1
	Leukocytosis	1	1	1	1
	Thrombocytopenia	1	1	1	1
	SOC Subtotal	3	3	3	3
Cardiac disorders	Arrhythmia	1	1	1	1
	Bradycardia	1	1	1	1
	Cardiac arrest	1	1	1	1
	Cardio-respiratory arrest	5	5	5	5
	Pulseless electrical activity	1	1	1	1
	SOC Subtotal	9	9	9	9
Gastrointestinal disorders	Ascites	2	2	2	2
	Intestinal infarction	2	2	2	2
	SOC Subtotal	4	4	4	4



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:23 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: 62

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
General disorders and administration site conditions	Accidental death	3	3	3	3
	Death	6	6	6	6
	Disease progression	1	1	1	1
	Drug interaction	16	16	16	16
	Drug withdrawal syndrome	1	1	1	1
	Fatigue	2	2	2	2
	Malaise	1	1	1	1
	Multiple organ dysfunction syndrome	1	1	1	1
	Oedema	1	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



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:23 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: 62

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Immune system disorders	Reaction to excipient	1	1	1	1
	SOC Subtotal	1	1	1	1
Injury, poisoning and procedural complications	Abdominal injury	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
	Fall	2	2	2	2
	Hip fracture	1	1	1	1
	Incorrect route of product administration	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



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:23 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: 62

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Injury, poisoning and procedural complications	Off label use	3	3	3	3
	Overdose	15	15	15	15
	Pelvic fracture	1	1	1	1
	Poisoning	3	3	3	3
	Prescribed overdose	2	2	2	2
	Product use in unapproved indication	3	3	3	3
	Road traffic accident	1	1	1	1
	Toxicity to various agents	20	20	20	20
	Wrist fracture	1	1	1	1
	Wrong patient received product	2	2	2	2
SOC Subtotal		65	65	65	65



Canada Vigilance Summary of Product Adverse Reactions

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

		2021			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Investigations	Analgesic drug level	1	1	1	1
	Antasthmatic drug level	1	1	1	1
	Benzodiazepine drug level therapeutic	1	1	1	1
	Blood ethanol increased	1	1	1	1
	Opiates positive	2	2	2	2
	Postmortem blood drug level abnormal	1	1	1	1
	Postmortem blood drug level increased	1	1	1	1
SOC Subtotal		8	8	8	8



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:23 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: 62

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

SOC	PT	2021		Total All Reactions	Total Outcome Fatal
		All Reactions	Outcome Fatal		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant cranial nerve neoplasm	1	1	1	1
	Metastases to liver	1	1	1	1
	Metastases to spine	1	1	1	1
	Neuroblastoma recurrent	1	1	1	1
	Retro-orbital neoplasm	1	1	1	1
SOC Subtotal		5	5	5	5



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:23 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: 62

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

		2021			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Nervous system disorders	Brain injury	1	1	1	1
	Brain oedema	2	2	2	2
	Dizziness	8	8	8	8
	Haemorrhage intracranial	1	1	1	1
	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
	SOC Subtotal	2	2	2	2



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:23 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: 62

Age: All

Gender: All

MedDRA Version:

Foreign or Domestic: Domestic

		2021			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Psychiatric disorders	Anxiety	1	1	1	1
	Depression	16	16	16	16
	Drug abuse	10	10	10	10
	Drug dependence	3	3	3	3
	Insomnia	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	1
	SOC Subtotal	2	2	2	2



Canada Vigilance Summary of Product Adverse Reactions

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

		2021			
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	Hypotension	1	1	1	1
	Orthostatic hypotension	1	1	1	1
	Pallor	1	1	1	1
	SOC Subtotal	3	3	3	3
	Grand Total	208	208	208	208



Canada Vigilance

Summary of Product Adverse Reactions

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 Occurrence	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 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

Term	Definition
Age	Age of the patient when the adverse reaction occurred. The age is unknown in some of the adverse reaction reports and age specific search terms are used where the age is unknown.
AR	Adverse Reaction
Gender	Gender of the patient as it was provided by the reporter. The gender is unknown in some of the adverse reaction reports and gender specific search terms are used where the gender is unknown.
Health Product	A health product includes drugs and natural health 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.
Dosage Form	All
Health Product Role	All
ATC	All
ATC Pattern	All
HLT	High Level Term – see definition of MedDRA
Reaction PTs	All
HLGT	High Level Group Term – see definition of MedDRA
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.



Health
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Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:08 AM
Health Product: See Search Criteria
Health Product Role:
Seriousness: All
Initial Date of Receipt: 2021-01-01 to 2021-12-31

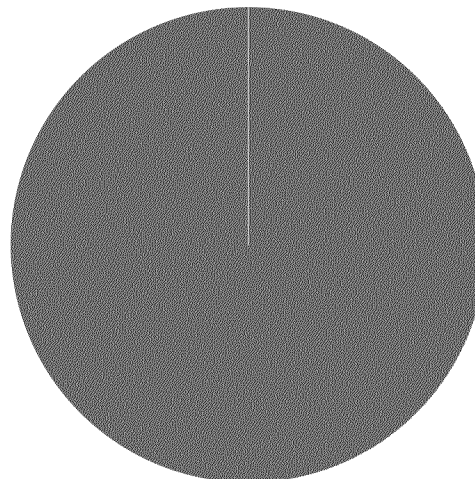
Total Number of Reports: 1
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

Total Number of Reactions	Total Number of AR Reports	Total Number of Serious AR Reports	Reason for Seriousness	
3	1	1	Death	1
			Life Threatening	0
			Hospitalization required	0
			Disability	0
			Congenital Anomaly	0
			Other Medically Important Condition	1

Age Group		
ADULT	1	100.00%

Age Group		
-----------	--	--

Patient Sex		
Female	1	100.00%



■ 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
Canada

Santé
Canada

Canada Vigilance Summary of Product Adverse Reactions

Report Runtime: 2022-02-16 11:08 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: 1
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

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

*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 11:08 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: 1
Age: All
Gender: All
MedDRA Version:
Foreign or Domestic: Domestic

System Organ Class	Number of All Reactions*	Number of Reactions* where outcome of report was fatal
HLGT		
HLT PT		

Injury, poisoning and procedural complications

Exposures, chemical injuries and poisoning

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

Psychiatric disorders

Psychiatric disorders NEC

Substance related and addictive disorders	Drug dependence	1	1
---	-----------------	---	---

Psychiatric disorders SOC Total

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).



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime:	2022-02-16 11:08 AM	Total Number of Reports:	1
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			
		December			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Injury, poisoning and procedural complications	Overdose	1	1	1	1
	Toxicity to various agents	1	1	1	1
	SOC Subtotal	2	2	2	2
Psychiatric disorders	Drug dependence	1	1	1	1
	SOC Subtotal	1	1	1	1
	Grand Total	3	3	3	3



Canada Vigilance Summary of Product Adverse Reactions

Report Runtime:

2022-02-16 11:08 AM

Total Number of Reports:

1

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			
SOC	PT	All Reactions	Outcome Fatal	Total All Reactions	Total Outcome Fatal
Injury, poisoning and procedural complications	Overdose	1	1	1	1
	Toxicity to various agents	1	1	1	1
	SOC Subtotal	2	2	2	2
Psychiatric disorders	Drug dependence	1	1	1	1
	SOC Subtotal	1	1	1	1
	Grand Total	3	3	3	3