



Patient Information Sheet

Olanzapine/Fluoxetine (marketed as Symbyax)

This is a summary of the most important information about Symbyax. For details, talk to your healthcare professional.

FDA ALERT [07/2006] – Possible Life- Threatening Serotonin Syndrome When Used With Triptan Medicines

A life-threatening condition called serotonin syndrome can happen when medicines called selective serotonin reuptake inhibitors (SSRIs), such as fluoxetine, one of the medicines in Symbyax, and medicines used to treat migraine headaches known as 5-hydroxytryptamine receptor agonists (triptans), are used together. Signs and symptoms of serotonin syndrome include the following:

- restlessness
- hallucinations
- loss of coordination
- fast heart beat
- increased body temperature
- fast changes in blood pressure
- Overactive reflexes
- diarrhea
- coma
- nausea
- vomiting

Serotonin syndrome may be more likely to occur when starting or increasing the dose of an SSRI or a triptan. This information comes from reports sent to FDA and knowledge of how these medicines work. If you take migraine headache medicines, ask your healthcare professional if your medicine is a triptan. Before you take Symbyax and a triptan together, talk to your healthcare professional. If you must take these medicines together, be aware of the possibility of serotonin syndrome, and get medical care right away if you think serotonin syndrome is happening to you.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available

FDA ALERT [06/2006] – Infant Persistent Pulmonary Hypertension

The results of a study that looked at the use of antidepressant medicines during pregnancy in mothers of babies born with a serious condition called persistent pulmonary hypertension of the newborn (PPHN) were recently published in a medical journal.

Babies born with PPHN have abnormal blood flow through the heart and lungs and do not get enough oxygen to their bodies. Babies with PPHN can be very sick and may die.

The study results showed that:

- babies born to mothers who took selective serotonin reuptake inhibitors (SSRIs), one of the medicines in Symbyax,
- 20 weeks or later in their pregnancies,
- had a higher chance (were 6 times as likely) to have persistent pulmonary hypertension (PPHN),
- than babies born to mothers who did not take antidepressants during pregnancy.

The FDA plans to further look at the role of SSRIs in babies with PPHN.

Talk to your doctor if you are taking Symbyax and are pregnant or are planning to have a baby. You and your doctor will need to talk about the best way to treat your depression during pregnancy.

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What Is Symbyax?

- Symbyax contains two medicines, olanzapine and fluoxetine. Olanzapine is in a class of medications called atypical antipsychotics. Antipsychotic medicines are used to treat symptoms of schizophrenia that may include hearing voices, seeing things, or sensing things that are not there, mistaken beliefs or unusual suspiciousness. Fluoxetine is in a class of medications called selective serotonin reuptake inhibitors (SSRIs). It is used to treat depression, obsessive-compulsive disorder, bulimia, and panic disorder.
- Symbyax is used to treat adults who have depression with bipolar disorder. Bipolar disorder is a mental illness that causes extreme mood swings.

Who Should Not Take Symbyax?

Never take Symbyax if you are taking another drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking an MAOI in the last 14 days. Taking Symbyax close in time to an MAOI can result in serious, sometimes fatal, reactions, including:

- High body temperature
- Coma
- Seizures (convulsions)

Do not take a MAOI within 5 weeks of stopping Symbyax. MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxazid), and other brands.

Never take Symbyax if you are taking Mellaril (thioridazine), used to treat schizophrenia. Also, do not take Mellaril within 5 weeks of stopping Symbyax. Taking Symbyax close in time to Mellaril can result in serious heart beat problems.

What are The Risks?

The following are the risks and potential side effects of Symbyax therapy. However, this list is not complete.

Symbyax can cause serious problems such as:

- **Suicidal thoughts or actions.** Persons taking Symbyax may be more likely to think about killing themselves or actually try to do so, especially when Prozac is first started or the dose is changed. People close to persons taking Prozac can help by paying attention to changes in user's moods or actions. Contact your healthcare

professional right away if someone using Prozac talks about or shows signs of killing him or herself. If you are taking Prozac yourself and you start thinking about killing yourself, tell your healthcare professional about this side effect right away.

- **Increased chance of death in elderly persons.** Elderly patients treated with atypical antipsychotics, such as Symbyax, for dementia had a higher chance for death than patients who did not take the medicine. Symbyax is not approved for dementia.
- **A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS).** NMS can cause a high fever, stiff muscles, sweating, a fast or irregular heart beat, change in blood pressure, and confusion. NMS can affect your kidneys. NMS is a medical emergency. Call your healthcare professional right away if you experience these symptoms.
- **A movement problem called tardive dyskinesia (TD).** Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- **High blood sugar and diabetes.** Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.
- **Strokes** have happened in older patients treated for mental illness from dementia. Symbyax is not approved for this use.
- **Bleeding problems.** Symbyax may cause bleeding problems, especially if taken with aspirin, NSAIDs (nonsteroidal antiinflammatory drugs, such as ibuprofen or naproxen), or other drugs that affect bleeding.
- **Sexual problems.** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- **Mania.** You may become hyperactive, excitable or elated.
- **Low salt levels in the blood.** Weakness, confusion, or trouble thinking can be caused by low salt levels in the blood.
- **Other serious side effects** may include low blood pressure seen as dizziness, and possibly fainting; increased heart beat; seizures; liver problems; increased body temperature; and difficulty swallowing.





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- **The most common side effects include** sleepiness, dry mouth, dizziness, restlessness, diarrhea, weight gain, increased appetite, and tremor.

What Should I Tell My Healthcare Professional?

Before you start using Symbyax, tell your healthcare professional if you:

- have or had heart problems
- have or had seizures
- have or had diabetes or increased blood sugar
- have or had liver disease
- are trying to become pregnant, are already pregnant, or are breast-feeding
- are taking fluoxetine, Prozac, Prozac Weekly, Sarafem, olanzapine, Zyprexa, or Zyprexa Zydis. These medicines each contain an ingredient that is also found in Symbyax.
- drink alcohol

Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with Symbyax, review all medications that you are taking with your healthcare professional, including those that you take without a prescription. Your healthcare professional may have to adjust your dose or watch you more closely if you take the following medications:

- blood pressure medicines
- levodopa and other medicines called dopamine agonists
- omeprazole
- rifampin
- carbamazepine
- fluvoxamine
- clozapine
- haloperidol
- phenytoin
- lithium
- pimozide
- sumatriptan
- warfarin

Avoid drinking alcohol while taking Symbyax.

Is There Anything Else I Need to Know?

- Dizziness, and sometimes fainting, caused by a drop in blood pressure may happen with Symbyax, especially when you first start taking this medicine or when the dose is increased.
- Symbyax may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how Symbyax affects you.
- It is important to avoid overheating and dehydration while taking Symbyax. Symbyax may make it harder to lower your body temperature.

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