

Patient Education

OLANZAPINE/FLUOXETINE - ORAL

IMPORTANT NOTE: The following information is intended to supplement, not substitute for, the expertise and judgment of your physician, pharmacist or other healthcare professional. It should not be construed to indicate that use of the drug is safe, appropriate, or effective for you. Consult your healthcare professional before using this drug.

OLANZAPINE/FLUOXETINE - ORAL

(oh-LAN-zuh-peen/flew-OX-eh-teen)

COMMON BRAND NAME(S): Symbyax

USES:

This medication is a combination of two drugs, olanzapine (an antipsychotic drug) and fluoxetine (a selective serotonin reuptake inhibitor or SSRI). It is used to treat a certain type of mental/emotional disorder (depression associated with bipolar disorder).

It works by helping to restore the balance of certain natural chemicals in the brain (neurotransmitters).

HOW TO USE:

Take this medication by mouth usually once daily in the evening, with or without food; or as directed by your doctor.

The dosage is based on your medical condition and response to therapy.

Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day.

It may take up to several weeks before the full benefit of this drug takes effect. It is important to continue taking this medication as prescribed even if you feel well. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when the drug is abruptly stopped. Your dose may need to be gradually decreased.

If your condition persists or worsens, contact your doctor or pharmacist.

Read the Patient Information Leaflet available from your pharmacist. Consult your doctor or pharmacist if you have any questions.

SIDE EFFECTS:

Dizziness, drowsiness, diarrhea, dry mouth, increased appetite, weight gain, trouble sleeping, or joint pain may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

To minimize dizziness or fainting, stand up slowly when rising from a seated or lying position; especially when you first start using this medication.

Tell your doctor immediately if any of these unlikely but serious side effects occur: black stools, changes in sexual ability, "coffee ground" vomit, easy bruising/bleeding, any mental/mood changes (e.g., confusion, trouble concentrating), weakness.

Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: fever, muscle stiffness, unusual decrease in the amount of urine, facial or body muscle twitching, lip smacking/other uncontrolled movements, tremor, weakness on one side of body, irregular/fast heartbeat, difficulty swallowing, seizures.

This drug may infrequently make your blood sugar level rise, which may cause or worsen diabetes. This high blood sugar can rarely cause serious (sometimes fatal) conditions such as diabetic coma. Tell your doctor immediately if you develop symptoms of high blood sugar, such as unusual increased thirst and urination, or vision changes. If you already have diabetes, be sure to check your blood sugars regularly.

This drug may also cause significant weight gain and a rise in your blood cholesterol (or triglyceride) levels. These effects, along with diabetes, may increase your risk for developing heart disease. Discuss the risks and benefits of treatment with your doctor. (See also Notes section.)

Males: In the very unlikely event you have a painful, prolonged erection, stop using this drug and seek immediate medical attention or permanent problems could occur.

A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing.

If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS:

Before taking olanzapine/fluoxetine, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: breast cancer, diabetes, heart disease, intestinal problems, kidney disease, liver problems, low blood pressure, narrow angle glaucoma, prostate problems, seizures, stomach/intestinal ulcers, stroke.

This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Avoid alcoholic beverages.

Though uncommon, depression can lead to thoughts or attempts of suicide. Tell your doctor immediately if you have any suicidal thoughts, worsening depression, or any other mental/mood changes (including new or worsening anxiety, agitation, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, rapid speech). Keep all medical appointments so your healthcare professional can monitor your progress closely and adjust/change your medication if needed.

This medication can reduce sweating which makes overheating more likely to occur. Avoid activities that might cause you to overheat (e.g., doing strenuous work, exercising in hot weather, or using hot tubs). Drink plenty of fluids to avoid becoming dehydrated.

Caution is advised when using this product in the elderly because they may be more sensitive to its side effects. The elderly are more likely to develop a type of mineral imbalance (hyponatremia), especially if they are also taking "water pills" or diuretics with this medication.

This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor.

If this medication is used during the last 3 months of pregnancy, infrequently your newborn may develop symptoms including feeding or breathing difficulties, seizures, muscle stiffness, jitteriness or constant crying. However, do not stop taking this medication unless your doctor directs you to do so. Report any such symptoms to your doctor promptly.

One of the drugs (fluoxetine) in this product passes into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Certain medications taken with this product could result in serious, even fatal, drug interactions. Avoid taking MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, selegiline, tranylcypromine) within 2 weeks of starting this medication, or at least 5 weeks after stopping it.

Also avoid taking thioridazine with this product or within 5 weeks after stopping treatment with olanzapine/fluoxetine. Consult your doctor or pharmacist for more information.

This drug should not be used with the following medications because very serious (possibly fatal) interactions may occur: astemizole, terfenadine, weight loss drugs (e.g., sibutramine, phentermine).

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: anti-anxiety medicines (e.g., diazepam), antiarrhythmics (e.g., flecainide, propafenone), other antidepressants (e.g., nefazodone, trazodone, venlafaxine), certain anti-seizure drugs (e.g., carbamazepine, phenytoin), aripiprazole, atomoxetine, clozapine, other drugs which can cause bleeding/bruising (e.g., thrombolytic drugs such as TPA, anticoagulants such as heparin or warfarin, antiplatelet drugs including NSAIDs such as ibuprofen), haloperidol, herbal/natural products (e.g., St John's wort, ayahuasca), drugs used for high blood pressure, lithium, medicines for Parkinson's disease, tramadol, tricyclic antidepressants (e.g., amitriptyline), "triptan" migraine drugs (e.g., sumatriptan, zolmitriptan), tryptophan, vinblastine.

Low-dose aspirin (usually 81-325 mg per day) for heart attack or stroke prevention should be continued unless your doctor instructs you otherwise. Aspirin is similar to NSAID drugs, and can increase the risk of bleeding in combination with this medication (see above). Discuss the risks and benefits with your doctor.

Tell your doctor or pharmacist if you also take drugs that cause drowsiness such as: antihistamines that cause drowsiness (e.g., diphenhydramine), medicine for sleep (e.g., sedatives), muscle relaxants, narcotic pain relievers (e.g., codeine), psychiatric medicines (e.g., phenothiazines such as chlorpromazine), tranquilizers.

Check the labels on all your medicines (e.g., cough-and-cold products) because they may contain drowsiness-causing ingredients. Ask your pharmacist about the safe use of those products.

Cigarette smoking decreases blood levels of this medication (hepatic enzyme induction). Tell your doctor if you smoke or if you have recently stopped smoking.

Do not start or stop any medicine without doctor or pharmacist approval.

OVERDOSE:

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include loss of consciousness or coma.

NOTES:

Do not share this medication with others.

Laboratory and/or medical tests (e.g., liver function tests, fasting blood sugar-FBS, weight, blood pressure, blood cholesterol/triglyceride levels) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

Obtain regular eye exams as part of your regular health care, and to check for any unlikely, but possible, eye problems.

MISSED DOSE:

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

MEDICAL ALERT: Your condition can cause complications in a medical emergency. For enrollment information call MedicAlert at 1-800-854-1166 (USA) or 1-800-668-1507 (Canada).