

MEDICATION GUIDE

Olanzapine and Fluoxetine Capsules, USP

(oh-LAN-zah-peen and floo-OX-eh-teen)

Read the Medication Guide that comes with olanzapine and fluoxetine capsules before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment. Talk with your doctor or pharmacist if there is something you do not understand or you want to learn more about olanzapine and fluoxetine capsules.

What is the most important information I should know about olanzapine and fluoxetine capsules?

Olanzapine and fluoxetine capsules may cause serious side effects, including:

1. **Suicidal thoughts or actions.**
2. **Increased risk of death in elderly people who are confused, have memory loss and have lost touch with reality (dementia-related psychosis).**
3. **High blood sugar (hyperglycemia).**
4. **High fat levels in your blood (increased cholesterol and triglycerides), especially in children and adolescents age 10 to 17.**
5. **Weight gain, especially in children and adolescents age 10 to 17.**

These serious side effects are described below.

1. **Suicidal thoughts or actions.**

Antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions:

Talk to your, or your family member's, healthcare provider about:

- all risks and benefits of treatment with antidepressant medicines.
- all treatment choices for depression or other serious mental illness.
- **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
- **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
- **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
- Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- or other unusual changes in behavior or mood.

What else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
 - **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
 - **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
 - **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
 - **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information.
2. **Increased risk of death in elderly people who are confused, have memory loss and have lost touch with reality (dementia-related psychosis).** Olanzapine and fluoxetine capsules are not approved for treating psychosis in elderly people with dementia.
 3. **High blood sugar (hyperglycemia):** High blood sugar can happen if you have diabetes already or if you have never had diabetes. High blood sugar could lead to:
 - build up of acid in your blood due to ketones (ketoacidosis)
 - coma
 - death

Your doctor should do tests to check your blood sugar before you start taking olanzapine and fluoxetine capsules and during treatment. In people who do not have diabetes, sometimes high blood sugar goes away when olanzapine and fluoxetine capsules are stopped. People with diabetes and some people who did not have diabetes before taking olanzapine and fluoxetine capsules need to take medicine for high blood sugar even after they stop taking olanzapine and fluoxetine capsules.

If you have diabetes, follow your doctor's instructions about how often to check your blood sugar while taking olanzapine and fluoxetine capsules.

Call your doctor if you have any of these symptoms of high blood sugar (hyperglycemia) while taking olanzapine and fluoxetine capsules:

- feel very thirsty

- need to urinate more than usual
- feel very hungry
- feel weak or tired
- feel sick to your stomach
- feel confused, or your breath smells fruity.

4. High fat levels in your blood (increased cholesterol and triglycerides). High fat levels may happen in people treated with olanzapine and fluoxetine capsules, especially in children and adolescents (10 to 17 years old). You may not have any symptoms, so your doctor should do blood tests to check your cholesterol and triglyceride levels before you start taking olanzapine and fluoxetine capsules and during treatment.

5. Increase in weight (weight gain): Weight gain is common in people who take olanzapine and fluoxetine capsules. Children and adolescents (10 to 17 years old) who received olanzapine and fluoxetine capsules, were more likely to gain weight and to gain more weight than adults. Some people may gain a lot of weight while taking olanzapine and fluoxetine capsules, so you and your doctor should check your weight regularly. Talk to your doctor about ways to control weight gain, such as eating a healthy, balanced diet, and exercising

What are olanzapine and fluoxetine capsules?

Olanzapine and fluoxetine capsules are a prescription medicine used for:

- short-term treatment of episodes of depression that happen with Bipolar I Disorder.

Olanzapine and fluoxetine capsules contain two medicines, olanzapine and fluoxetine hydrochloride.

It is not known if olanzapine and fluoxetine capsules are safe and effective in children under the age of 10.

The symptoms of Bipolar I Disorder include alternating periods of depression and high or irritable mood, increased activity and restlessness, racing thoughts, talking fast, impulsive behavior, and a decreased need for sleep. With treatment, some of your symptoms of Bipolar I Disorder may improve.

If you do not think you are getting better, call your doctor.

Who should not take olanzapine and fluoxetine capsules?

- Do not take olanzapine and fluoxetine capsules if you take a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
- Do not take an MAOI **within 5 weeks of stopping olanzapine and fluoxetine capsules.** unless directed to do so by your physician.
- Do not start olanzapine and fluoxetine capsules. if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

People who take olanzapine and fluoxetine capsules close in time to an MAOI can have serious and life-threatening side effects, with symptoms including:

- high fever
- continued muscle spasms that you cannot control
- rigid muscles
- changes in heart rate and blood pressure that happen fast
- confusion
- unconsciousness.
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Do not take olanzapine and fluoxetine capsules if you take Mellaril[®] (thioridazine). Do not take Mellaril[®] **within 5 weeks of stopping olanzapine and fluoxetine capsules. Mellaril can cause serious heart rhythm problems and you could die suddenly.**

- Do not take olanzapine and fluoxetine capsules if you take the antipsychotic medicine pimozide (Orap[®]). Do not take pimozide (Orap[®]) **within 5 weeks of stopping olanzapine and fluoxetine capsules.**

What should I tell my doctor before taking olanzapine and fluoxetine capsules?

Olanzapine and fluoxetine capsules may not be right for you. Before starting olanzapine and fluoxetine capsules, tell your doctor about all your medical conditions, including if you have or had any of the following:

- heart problems
- seizures (convulsions)
- diabetes or high blood sugar levels (hyperglycemia)
- high cholesterol or triglyceride levels in your blood
- liver problems
- low or high blood pressure
- strokes or “mini-strokes” also called transient ischemic attacks (TIAs)
- bleeding problems
- Alzheimer's disease
- angle-closure glaucoma
- enlarged prostate in men
- bowel obstruction
- breast cancer
- are pregnant or plan to become pregnant. It is not known if olanzapine and fluoxetine capsules will harm your unborn baby.
- are breast-feeding or plan to breast-feed. Olanzapine and fluoxetine can pass into your breast milk and may harm your baby. You should not breast-feed while taking olanzapine and fluoxetine capsules. Talk to your doctor about the best way to feed your baby if you take olanzapine and fluoxetine capsules.

Before starting olanzapine and fluoxetine capsules, **tell your doctor about all the medicines that you take, including:**

- Prescription and non-prescription medicines
- Vitamins, and herbal supplements.
- Triptans used to treat migraine headache
- Medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, buspirone, SSRIs, SNRIs, MAOIs, or antipsychotics
- Tramadol and fentanyl
- Amphetamines
- Over-the-counter supplements such as tryptophan or St. John's Wort
- Electroconvulsive therapy (ECT)

Olanzapine and fluoxetine capsules and some medicines may interact with each other and may not work as well, or cause possible serious side effects. Your doctor can tell you if it is safe to take olanzapine and fluoxetine capsules with your other medicines. Do not start or stop any medicine while taking olanzapine and fluoxetine capsules without talking to your doctor first.

If you take olanzapine and fluoxetine capsules, you should not take any other medicines that contain:

- olanzapine (the active ingredient in Zyprexa[®] and Zyprexa[®] Zydys[®]) or
- fluoxetine hydrochloride (the active ingredient in Prozac[®], Prozac[®] Weekly[™], and Sarafem[®]).

You could take too much medicine (overdose).

How should I take olanzapine and fluoxetine capsules?

- Take olanzapine and fluoxetine capsules exactly as prescribed. Your doctor may need to change (adjust) the dose of olanzapine and fluoxetine capsules until it is right for you.
- If you miss a dose of olanzapine and fluoxetine capsules, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of olanzapine and fluoxetine capsules at the same time.
- **To prevent serious side effects, do not stop taking olanzapine and fluoxetine capsules suddenly. If you need to stop taking olanzapine and fluoxetine capsules, your doctor can tell you how to safely stop taking it.**
- **If you take too many olanzapine and fluoxetine capsules, call your doctor or poison control center right away, or get emergency treatment.**
- Olanzapine and fluoxetine capsules can be taken with or without food.
- Olanzapine and fluoxetine capsules are usually taken one time each day, in the evening.
- If you do not think you are getting better or have any concerns about your condition while taking olanzapine and fluoxetine capsules, call your doctor.

What should I avoid while taking olanzapine and fluoxetine capsules?

- Olanzapine and fluoxetine capsules can cause sleepiness and may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how olanzapine and fluoxetine capsules affects you.
- Avoid drinking alcohol while taking olanzapine and fluoxetine capsules. Drinking alcohol while you take olanzapine and fluoxetine capsules may make you sleepier than if you take olanzapine and fluoxetine capsules alone.

What are the possible side effects of olanzapine and fluoxetine capsules?

Other possible serious risks:

- **Increased risk of death and increased incidence of stroke or “mini-strokes” called transient ischemic attacks (TIAs) in elderly people with psychosis related to dementia** (a brain disorder that lessens the ability to remember, think, and reason). Olanzapine and fluoxetine capsules are not approved for these patients.
- **Severe allergic reactions:** Tell your doctor right away if you get red itchy welts (hives) or, a rash alone or with fever and joint pain, while taking olanzapine and fluoxetine capsules. Call your doctor right away if you become severely ill and have some or all of these symptoms:
 - swelling of your face, eyes, or mouth
 - trouble breathing
- **Neuroleptic malignant syndrome (NMS):** NMS is a rare but very serious condition that can happen in people who take antipsychotic medicines, including olanzapine and fluoxetine capsules. NMS can cause death and must be treated in a hospital. Call your doctor right away if you become severely ill and have some or all of these symptoms:
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- high fever
 - excessive sweating
 - rigid muscles
 - confusion
 - changes in your breathing, heartbeat, and blood pressure
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):** DRESS can occur. Features of DRESS may include rash, fever, swollen glands and other internal organ involvement such as liver, kidney, lung and heart. DRESS is sometimes fatal; therefore, tell your doctor immediately if you experience any of these signs.
- **Tardive Dyskinesia:** This condition causes body movements that keep happening and that you cannot control. These movements usually affect the face and tongue. Tardive dyskinesia may not go away, even if you stop taking olanzapine and fluoxetine capsules. It may also start after you stop taking olanzapine and fluoxetine capsules. Tell your doctor if you get any body movements that you cannot control.
- **Serotonin Syndrome:** This is a condition that can be life threatening. Call your doctor right away if you become severely ill and have some or all of these symptoms:
 - agitation, hallucinations, coma or other changes in mental status
 - coordination problems or muscle twitching (overactive reflexes)
 - racing heartbeat, high or low blood pressure
 - sweating or fever
 - nausea, vomiting, and diarrhea
 - muscle rigidity
 - dizziness
 - flushing
 - tremor
 - seizures
- **Visual problems:**
 - eye pain
 - changes in vision
 - swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

- **Abnormal bleeding:** Tell your doctor if you notice any increased or unusual bruising or bleeding while taking olanzapine and fluoxetine capsules, especially if you take one of these medicines:
 - the blood thinner warfarin (Coumadin, Jantoven)
 - a non-steroidal anti-inflammatory drug (NSAID)
 - aspirin
- **Low salt (sodium) levels in the blood (hyponatremia):** Call your doctor right away if you become severely ill and have some or all of these symptoms:
 - headache
 - feel weak

- confusion
 - problems concentrating
 - memory problems
 - feel unsteady
- **Changes in the electrical activity of your heart (QT prolongation and ventricular arrhythmia including Torsade de Pointes).** This condition can be life threatening. The symptoms may include:
 - fast, slow, or irregular heartbeat
 - shortness of breath
 - dizziness or fainting
 - **Decreased blood pressure when you change positions, with symptoms of dizziness, fast or slow heart beat, or fainting**
 - **Difficulty swallowing**
 - **Seizures**
 - **Problems with control of body temperature:** You could become very hot, for instance when you exercise a lot or stay in an area that is very hot. It is important for you to drink water to avoid dehydration. Call your doctor right away if you become severely ill and have some or all of these symptoms of dehydration:
 - sweating too much or not at all
 - dry mouth
 - feeling very hot
 - feeling thirsty
 - not able to produce urine

Common possible side effects of olanzapine and fluoxetine capsules include: dry mouth, tiredness, sleeping for long period of time, increased appetite, swelling of your hands and feet, drowsiness, tremors (shakes), or blurred vision.

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects with olanzapine and fluoxetine capsules. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088.

How should I store olanzapine and fluoxetine capsules?

- Store olanzapine and fluoxetine capsules at 68° to 77°F (20° to 25°C).
- Keep olanzapine and fluoxetine capsules away from light.
- Keep olanzapine and fluoxetine capsules dry and away from moisture. Keep the bottle closed tightly.

Keep olanzapine and fluoxetine capsules and all medicines out of the reach of children.

General information about olanzapine and fluoxetine capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use olanzapine and fluoxetine capsules for a condition for which it was not prescribed. Do not give olanzapine and fluoxetine capsules to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about olanzapine and fluoxetine capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about olanzapine and fluoxetine capsules that was written for healthcare professionals. For more information about olanzapine and fluoxetine capsules, call Sandoz Inc. at 1-800-525-8747.

What are the ingredients in olanzapine and fluoxetine capsules?

Active ingredients: Olanzapine and fluoxetine hydrochloride

Inactive ingredients: Each capsule contains pregelatinized starch.

The capsule shell for the 3 mg/25 mg strength consists of gelatin, FDA/E172 yellow iron oxide, FDA/E172 red iron oxide, titanium dioxide. The black ink is comprised of black iron oxide, potassium hydroxide, propylene glycol, shellac.

The capsule shell for the 6 mg/25 mg strength consists of D&C red # 28, D&C yellow # 10, FDA/E172 yellow iron oxide, gelatin, titanium dioxide. The black ink is comprised of black iron oxide, potassium hydroxide, propylene glycol, shellac.

The capsule shell for the 6 mg/50 mg strength consists of D&C red # 28, D&C yellow # 10, gelatin, FDA/E172 black iron oxide, titanium dioxide. The black ink is comprised of black iron oxide, potassium hydroxide, propylene glycol, shellac.

The capsule shell for the 12 mg/25 mg strength consists of FDA/E172 yellow iron oxide, FD&C Red # 3, red iron oxide, gelatin, titanium dioxide. The black ink is comprised of black iron oxide, potassium hydroxide, propylene glycol, shellac.

The capsule shell for the 12 mg/50 mg strength consists of FDA/E172 black iron oxide, FD&C Red # 3, red iron oxide, gelatin, titanium dioxide. The black ink is comprised of black iron oxide, potassium hydroxide, propylene glycol, shellac.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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