

Medication Guide

Olanzapine Tablets, USP (oh lan' za peen)

Medication Guide available at www1.apotex.com/products/us

Read the Medication Guide that comes with olanzapine tablets 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 tablets.

What is the most important information I should know about olanzapine tablets?

Olanzapine tablets may cause serious side effects, including:

1. **Increased risk of death in elderly people who are confused, have memory loss and have lost touch with reality (dementia-related psychosis).**
2. **High blood sugar (hyperglycemia).**
3. **High fat levels in your blood (increased cholesterol and triglycerides), especially in teenagers age 13 to 17 or when used in combination with fluoxetine in children age 10 to 17.**
4. **Weight gain, especially in teenagers age 13 to 17 or when used in combination with fluoxetine in children age 10 to 17.**

These serious side effects are described below.

1. **Increased risk of death in elderly people who are confused, have memory loss and have lost touch with reality (dementia-related psychosis).** Olanzapine tablets are not approved for treating psychosis in elderly people with dementia.
2. **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:
 - a 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 tablets and during treatment. In people who do not have diabetes, sometimes high blood sugar goes away when olanzapine tablets are stopped. People with diabetes and some people who did not have diabetes before taking olanzapine tablets need to take medicine for high blood sugar even after they stop taking olanzapine tablets.

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

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

- 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

3. High fat levels in your blood (cholesterol and triglycerides). High fat levels may happen in people treated with olanzapine tablets, especially in teenagers (13 to 17 years old), or when used in combination with fluoxetine in children (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 tablets and during treatment.

4. Weight gain. Weight gain is very common in people who take olanzapine tablets. Teenagers (13 to 17 years old) are more likely to gain weight and to gain more weight than adults. Children (10 to 17 years old) are also more likely to gain weight and to gain more weight than adults when olanzapine tablets are used in combination with fluoxetine. Some people may gain a lot of weight while taking olanzapine tablets, 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 tablets?

Olanzapine tablets are a prescription medicine used to treat:

- schizophrenia in people age 13 or older.
- bipolar disorder, including:
 - manic or mixed episodes that happen with bipolar I disorder in people age 13 or older.
 - manic or mixed episodes that happen with bipolar I disorder, when used with the medicine lithium or valproate, in adults.
 - long-term treatment of bipolar I disorder in adults.
- episodes of depression that happen with bipolar I disorder, when used with the medicine fluoxetine (Prozac®) in people age 10 or older.
- episodes of depression that do not get better after 2 other medicines, also called treatment resistant depression, when used with the medicine fluoxetine (Prozac), in adults.

Olanzapine tablets have not been approved for use in children under 13 years of age. Olanzapine in combination with fluoxetine has not been approved for use in children under 10 years of age.

The symptoms of schizophrenia include hearing voices, seeing things that are not there, having beliefs that are not true, and being suspicious or withdrawn.

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.

The symptoms of treatment resistant depression include decreased mood, decreased interest, increased guilty feelings, decreased energy, decreased concentration, changes in appetite, and suicidal thoughts or behavior.

Some of your symptoms may improve with treatment. If you do not think you are getting better, call your doctor.

What should I tell my doctor before taking olanzapine tablets?

Olanzapine tablets may not be right for you. Before starting olanzapine tablets, tell your doctor if you have or had:

- heart problems
- seizures
- 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)
- Alzheimer’s disease
- narrow-angle glaucoma
- enlarged prostate in men
- bowel obstruction
- breast cancer
- thoughts of suicide or hurting yourself
- any other medical condition
- are pregnant or plan to become pregnant. It is not known if olanzapine tablets will harm your unborn baby.
 - If you become pregnant while receiving olanzapine tablets, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to <http://womensmentalhealth.org/clinical-andresearch-programs/pregnancyregistry/>.
- are breast-feeding or plan to breast-feed. Olanzapine passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take olanzapine tablets.

Tell your doctor if you exercise a lot or are in hot places often.

The symptoms of bipolar I disorder, treatment resistant depression, or schizophrenia may include **thoughts of suicide** or of hurting yourself or others. If you have these thoughts at any time, tell your doctor or go to an emergency room right away.

Tell your doctor about all the medicines that you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Olanzapine tablets 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 tablets with your other medicines. Do not start or stop any medicine while taking olanzapine tablets without talking to your doctor first.

How should I take olanzapine tablets?

- Take olanzapine tablets exactly as prescribed. Your doctor may need to change (adjust) the dose of olanzapine tablets until it is right for you.
- If you miss a dose of olanzapine tablets, take the missed dose as soon as you remember. If it is almost time for the next dose, just skip the missed dose and take your next dose at the regular time. Do not take two doses of olanzapine tablets at the same time.
- **To prevent serious side effects, do not stop taking olanzapine tablets suddenly. If you need to stop taking olanzapine tablets, your doctor can tell you how to safely stop taking it.**

- **If you take too much olanzapine, call your doctor or poison control center at 1-800-222-1222 right away, or get emergency treatment.**
- Olanzapine tablets can be taken with or without food.
- Olanzapine tablets are usually taken one time each day.
- Call your doctor if you do not think you are getting better or have any concerns about your condition while taking olanzapine tablets.

What should I avoid while taking olanzapine tablets?

- Olanzapine tablets 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 tablets affects you.
- Avoid drinking alcohol while taking olanzapine tablets. Drinking alcohol while you take olanzapine tablets may make you sleepier than if you take olanzapine tablets alone.

What are the possible side effects of olanzapine tablets?

Serious side effects may happen when you take olanzapine tablets, including:

- **See “What is the most important information I should know about olanzapine tablets?”**, which describes the increased risk of death in elderly people with dementia-related psychosis and the risks of high blood sugar, high cholesterol and triglyceride levels, and weight gain.
- **Increased incidence of stroke or “mini-strokes” called transient ischemic attacks (TIAs) in elderly people with dementia-related psychosis** (elderly people who have lost touch with reality due to confusion and memory loss). Olanzapine tablets are not approved for these patients.
- **Neuroleptic Malignant Syndrome (NMS):** NMS is a rare but very serious condition that can happen in people who take antipsychotic medicines, including olanzapine tablets. NMS can cause death and must be treated in a hospital. Call your doctor right away if you become severely ill and have any of these symptoms:
 - 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 with olanzapine tablets. 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 can not control. These movements usually affect the face and tongue. Tardive dyskinesia may not go away, even if you stop taking olanzapine tablets. It may also start after you stop taking olanzapine tablets. Tell your doctor if you get any body movements that you can not control.
- **Decreased blood pressure when you change positions, with symptoms of dizziness, fast or slow heartbeat, or fainting.**
- **Difficulty swallowing, that can cause food or liquid to get into your lungs.**
- **Seizures: Tell your doctor if you have a seizure during treatment with olanzapine tablets.**

- **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 any 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 side effects of olanzapine tablets include: lack of energy, dry mouth, increased appetite, sleepiness, tremor (shakes), having hard or infrequent stools, dizziness, changes in behavior, or restlessness.

Other common side effects in teenagers (13 to 17 years old) include: headache, stomach-area (abdominal) pain, pain in your arms or legs, or tiredness. Teenagers experienced greater increases in prolactin, liver enzymes, and sleepiness, as compared with adults.

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 tablets. For more information, ask your doctor or pharmacist.

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

How should I store olanzapine tablets?

- Store olanzapine tablets at 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C to 30°C (59°F to 86°F).
- Keep olanzapine tablets away from light.
- Keep olanzapine tablets dry and away from moisture.

Keep olanzapine tablets and all medicines out of the reach of children.

General information about olanzapine tablets

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

This Medication Guide summarizes the most important information about olanzapine tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about olanzapine tablets that was written for healthcare professionals. For more information about olanzapine tablets call Apotex Corp. at 1-800-706-5575 or visit www.apotexcorp.com/products.

What are the ingredients in olanzapine tablets?

Active ingredient: olanzapine

Inactive ingredients: lactose, magnesium stearate, microcrystalline cellulose, starch. The color coating contains FD&C blue No.2 aluminum lake (15 mg), ferric oxide red (20 mg), hydroxypropyl

cellulose, hypromellose, iron oxide yellow (20 mg), polyethylene glycol and titanium dioxide (all strengths).

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

All registered trademarks in this document are the property of their respective owners.

APOTEX INC.

OLANZAPINE TABLETS, USP

2.5 mg, 5.0 mg, 7.5 mg, 10 mg, 15 mg and 20 mg

Manufactured by

Apotex Inc.
Toronto, Ontario
Canada M9L 1T9

Manufactured for

Apotex Corp.
Weston, Florida
USA 33326

Revised: June 2021

Revision 8