

Medication Guide

Olanzapine Orally Disintegrating Tablets (oh lan'za peen)

Read the Medication Guide that comes with olanzapine orally disintegrating 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 orally disintegrating tablets.

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

Olanzapine orally disintegrating 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 orally disintegrating 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 orally disintegrating tablets and during treatment.

In people who do not have diabetes, sometimes high blood sugar goes away when olanzapine orally disintegrating tablets are stopped.

People with diabetes and some people who did not have diabetes before taking olanzapine orally disintegrating tablets need to take medicine for high blood sugar even after they stop taking olanzapine orally disintegrating tablets.

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

Call your doctor if you have any of these symptoms of high blood sugar (hyperglycemia) while taking olanzapine orally disintegrating 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 orally disintegrating 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 orally disintegrating tablets and during treatment.

4. Weight gain. Weight gain is very common in people who take olanzapine orally disintegrating 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 orally disintegrating tablet is used in combination with fluoxetine. Some people may gain a lot of weight while taking olanzapine orally disintegrating 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 orally disintegrating tablets?

Olanzapine orally disintegrating 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 orally disintegrating tablets have not been approved for use in children under 13 years of age. Olanzapine orally disintegrating tablets 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 orally disintegrating tablets?

Olanzapine orally disintegrating tablets may not be right for you. Before starting olanzapine orally disintegrating 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
- phenylketonuria, because olanzapine orally disintegrating tablets contains phenylalanine
- 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 orally disintegrating tablets will harm your unborn baby.
- If you become pregnant while receiving olanzapine orally disintegrating 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-and-research-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 orally disintegrating 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 orally disintegrating 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 orally disintegrating tablets with your other medicines. Do not start or stop any medicine while taking olanzapine orally disintegrating tablets without talking to your doctor first.

