

Medication Guide

ZYPREXA[®] (zy-PREX-a)
(olanzapine)
Tablet

ZYPREXA[®] ZYDIS[®] (zy-PREX-a ZY-dis)
(olanzapine)
Tablet, Orally Disintegrating

Read the Medication Guide that comes with ZYPREXA 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 ZYPREXA.

What is the most important information I should know about ZYPREXA?

ZYPREXA may be associated with the following serious risks:

High blood sugar (hyperglycemia): High blood sugar can occur if you have diabetes already or even if you have never had diabetes. In rare cases, this could lead to ketoacidosis (build up of acid in the blood due to ketones), coma, or death. Your doctor should do lab tests to check your blood sugar before you start taking ZYPREXA and during treatment. In people who do not have diabetes, sometimes high blood sugar goes away when ZYPREXA is stopped. People with diabetes and some people who did not have diabetes before taking ZYPREXA need to take medicine for high blood sugar even after they stop taking ZYPREXA.

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

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

- 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.

High cholesterol and triglyceride levels in the blood (fat in the blood): These have been observed in patients treated with ZYPREXA, especially in teenagers (13-17 years old). ZYPREXA is not approved in patients less than 18 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 ZYPREXA and during treatment.

Increase in weight (weight gain): Weight gain is very commonly seen in patients who take ZYPREXA. Teenagers (13-17 years old) are more likely to gain weight and to gain more weight than adults. ZYPREXA is not approved in patients less than 18 years old. Some patients may gain a lot of weight while taking ZYPREXA, 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 is ZYPREXA?

ZYPREXA is a prescription medicine approved for use in adults:

- to treat schizophrenia.
- alone or with lithium or valproate for the short-term treatment of manic or mixed episodes that happen with Bipolar I Disorder.
- for long-term treatment of Bipolar I Disorder.
- with the medicine fluoxetine (Prozac[®]), for the short-term treatment of episodes of depression that happen with Bipolar I Disorder.
- with the medicine fluoxetine (Prozac), for the short-term treatment of episodes of depression that do not respond to 2 other medicines, also called treatment resistant depression.

It is not known if ZYPREXA is safe and works in children under 18 years of age.

It is not known if ZYPREXA taken with fluoxetine (Prozac) is safe and works in children under 18 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. With treatment, some of your symptoms of schizophrenia may improve.

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.

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. With treatment, some of your symptoms of treatment resistant depression may improve.

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

What should I tell my doctor before taking ZYPREXA?

ZYPREXA may not be right for you. Before starting ZYPREXA, 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)
- Alzheimer’s disease
- narrow-angle glaucoma
- enlarged prostate in men
- bowel obstruction
- phenylketonuria, because ZYPREXA® ZYDIS® contains phenylalanine
- breast cancer
- are pregnant or plan to become pregnant. It is not known if ZYPREXA will harm your unborn baby.
- are breast-feeding or plan to breast-feed. ZYPREXA can pass into your breast milk and may harm your baby. You should not breast-feed while taking ZYPREXA. Talk to your doctor about the best way to feed your baby if you take ZYPREXA.

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 non-prescription medicines, vitamins, and herbal supplements. ZYPREXA 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 ZYPREXA with your other medicines. Do not start or stop any medicine while taking ZYPREXA without talking to your doctor first.

How should I take ZYPREXA?

- Take ZYPREXA exactly as prescribed. Your doctor may need to change (adjust) the dose of ZYPREXA until it is right for you.
- If you miss a dose of ZYPREXA, 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 ZYPREXA at the same time.
- **To prevent serious side effects, do not stop taking ZYPREXA suddenly. If you need to stop taking ZYPREXA, your doctor can tell you how to safely stop taking it.**
- **If you take too much ZYPREXA, call your doctor or poison control center right away, or get emergency treatment.**
- ZYPREXA can be taken with or without food.
- ZYPREXA is usually taken one time each day.
- Take ZYPREXA ZYDIS as follows:
 - Be sure that your hands are dry.
 - Open the sachet and peel back the foil on the blister. Do not push the tablet through the foil.
 - As soon as you open the blister, remove the tablet and put it into your mouth.
 - The tablet will disintegrate quickly in your saliva so that you can easily swallow it with or without drinking liquid.
- If you do not think you are getting better or have any concerns about your condition while taking ZYPREXA, call your doctor.

What should I avoid while taking ZYPREXA?

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

What are the possible side effects of ZYPREXA?

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). ZYPREXA is 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 ZYPREXA. 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:
 - high fever
 - excessive sweating
 - rigid muscles
 - confusion
 - changes in your breathing, heartbeat, and blood pressure
- **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 ZYPREXA. It may also start after you stop taking ZYPREXA. Tell your doctor if you get any body movements that you cannot control.
- **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 ZYPREXA include: lack of energy, dry mouth, increased appetite, sleepiness, tremor (shakes), having hard or infrequent stools, dizziness, changes in behavior, or restlessness.

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 ZYPREXA. 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 ZYPREXA?

- Store ZYPREXA at room temperature, between 68°F to 77°F (20°C to 25°C).
- Keep ZYPREXA away from light.
- Keep ZYPREXA dry and away from moisture.

Keep ZYPREXA and all medicines out of the reach of children.

General information about ZYPREXA

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

This Medication Guide summarizes the most important information about ZYPREXA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ZYPREXA that was written for healthcare professionals. For more information about ZYPREXA call 1-800-Lilly-Rx (1-800-545-5979) or visit www.zyprexa.com.

What are the ingredients in ZYPREXA?

Active ingredient: olanzapine

Inactive ingredients:

Tablets — carnauba wax, crospovidone, hydroxypropyl cellulose, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, and other inactive ingredients. The color coating contains: Titanium Dioxide, FD&C Blue No. 2 Aluminum Lake, or Synthetic Red Iron Oxide.

ZYDIS — gelatin, mannitol, aspartame, sodium methyl paraben, and sodium propyl paraben.

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

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