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Source : U.S. National Library of Medicine

URL of this page: <https://medlineplus.gov/druginfo/meds/a601213.html>

## Olanzapine

pronounced as (oh lan' za peen)

### IMPORTANT WARNING:

Studies have shown that older adults with dementia (a brain disorder that affects the ability to remember, think clearly, communicate, and perform daily activities and that may cause changes in mood and personality) who take antipsychotics (medications for mental illness) such as olanzapine have an increased chance of death during treatment. Older adults with dementia may also have a greater chance of having a stroke or mini-stroke during treatment.

Olanzapine is not approved by the Food and Drug Administration (FDA) for the treatment of behavior disorders in older adults with dementia. Talk to the doctor who prescribed this medication if you, a family member, or someone you care for has dementia and is taking olanzapine. For more information visit the FDA website: <http://www.fda.gov/Drugs> [<http://www.fda.gov/Drugs>]

### Why is this medication prescribed?

Olanzapine is used to treat the symptoms of schizophrenia (a mental illness that causes disturbed or unusual thinking, loss of interest in life, and strong or inappropriate emotions) in adults and teenagers 13 years of age and older. It is also used to treat bipolar disorder (manic depressive disorder; a disease that causes episodes of depression, episodes of mania, and other abnormal moods) in adults and teenagers 13 years of age and older. Olanzapine is in a class of medications called atypical antipsychotics. It works by changing the activity of certain natural substances in the brain.

### How should this medicine be used?

Olanzapine comes as a tablet and an orally disintegrating tablet (tablet that dissolves quickly in the mouth) to take by mouth. It is usually taken once a day with or without food. Take olanzapine at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take olanzapine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Do not try to push the orally disintegrating tablet through the foil. Instead, use dry hands to peel back the foil packaging. Immediately take out the tablet and place it in your mouth. The tablet will quickly dissolve

and can be swallowed with or without liquid.

Your doctor may start you on a low dose of olanzapine and gradually increase your dose.

Olanzapine may help control your symptoms, but it will not cure your condition. It may take several weeks or longer before you feel the full benefit of olanzapine. Continue to take olanzapine even if you feel well. Do not stop taking olanzapine without talking to your doctor. Your doctor will probably want to decrease your dose gradually.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking olanzapine,

- tell your doctor and pharmacist if you are allergic to olanzapine or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: antidepressants; antihistamines; carbamazepine (Tegretol); dopamine agonists such as bromocriptine (Parlodel), cabergoline (Dostinex), levodopa (Dopar, Larodopa), pergolide (Permax), and ropinirole (Requip); fluoroquinolone antibiotics including ciprofloxacin (Cipro), gatifloxacin (Tequin) (not available in the United States), levofloxacin (Levaquin), norfloxacin (Noroxin), ofloxacin (Floxin), others; fluvoxamine (Luvox); ipratropium (Atrovent); medications for anxiety, high blood pressure, irritable bowel disease, mental illness, motion sickness, Parkinson's disease, seizures, ulcers, or urinary problems; omeprazole (Prilosec); rifampin (Rifadin); sedatives; sleeping pills; ticlopidine (Ticlid); and tranquilizers. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you use or have ever used street drugs or have overused prescription medications and if you have or have ever had a stroke, a mini-stroke, heart disease or a heart attack, an irregular heartbeat, heart failure, urinary problems, seizures, breast cancer, any condition that makes it difficult for you to swallow, trouble keeping your balance, high or low blood pressure, a high level of fats (cholesterol and triglycerides) in your blood, a low number of white blood cells, liver or prostate disease, paralytic ileus (condition in which food cannot move through the intestine); glaucoma (an eye condition), or high blood sugar, or if you or anyone in your family has or has ever had diabetes. Tell your doctor if you have constipation, severe vomiting or diarrhea or signs of dehydration now, or if you develop these symptoms at any time during your treatment. Also tell your doctor if you have ever had to stop taking a medication for mental illness because of severe side effects.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy, or if you plan to become pregnant or are breastfeeding. If you become pregnant while taking olanzapine, call your doctor. Olanzapine may cause problems in newborns following delivery if it is taken during the last months of pregnancy.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking olanzapine.
- you should know that olanzapine may make you drowsy. Do not drive a car or operate machinery until you know how this medication affects you.
- you should know that alcohol can add to the drowsiness caused by this medication. Do not drink alcohol while taking olanzapine.

- tell your doctor if you use tobacco products. Cigarette smoking may decrease the effectiveness of this medication.
- you should know that you may experience hyperglycemia (increases in your blood sugar) while you are taking this medication, even if you do not already have diabetes. If you have schizophrenia, you are more likely to develop diabetes than people who do not have schizophrenia, and taking olanzapine or similar medications may increase this risk. Tell your doctor immediately if you have any of the following symptoms while you are taking olanzapine: extreme thirst, frequent urination, extreme hunger, blurred vision, or weakness. It is very important to call your doctor as soon as you have any of these symptoms, because high blood sugar can cause a serious condition called ketoacidosis. Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include: dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.
- you should know that olanzapine may cause fast or slow heartbeat, dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. This is more common when you first start taking olanzapine. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- you should know that olanzapine may make it harder for your body to cool down when it gets very hot. Tell your doctor if you plan to do vigorous exercise or be exposed to extreme heat.
- if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent damage to your brain that can cause severe intellectual disability), you should know that the orally disintegrating tablets contain aspartame that forms phenylalanine.
- you should know that when olanzapine is used to treat teenagers, it must be used as part of a total treatment program that may include counseling and educational support. Make sure that your child follows all of the doctor's and/or therapist's instructions.

## What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medicine.

Be sure to drink plenty of water every day while you are taking this medication.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Olanzapine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- dizziness, feeling unsteady, or having trouble keeping your balance
- restlessness
- unusual behavior
- depression
- difficulty falling asleep or staying asleep

- weakness
- difficulty walking
- constipation
- weight gain
- dry mouth
- pain in arms, legs, back, or joints
- breast enlargement or discharge
- late or missed menstrual periods
- decreased sexual ability

**Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNING section or the SPECIAL PRECAUTIONS section, call your doctor immediately:**

- seizures
- changes in vision
- swelling of the arms, hands, feet, ankles, or lower legs
- unusual movements of your face or body that you cannot control
- falling
- sore throat, fever, chills, and other signs of infection
- very stiff muscles
- excess sweating
- fast or irregular heartbeat
- rash that may occur with fever, swollen glands, or swelling of the face
- skin redness or peeling
- hives
- difficulty breathing or swallowing

Olanzapine may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

Taking olanzapine may cause the level of fats in your blood to increase. Talk to your doctor about the risks of taking olanzapine.

Teenagers who take olanzapine are more likely than adults who take olanzapine to gain weight, have increased levels of fat in their blood, develop liver problems, and experience side effects such as sleepiness, breast enlargement, and discharge from the breasts. Talk to your child's doctor about the risks of treating your child with olanzapine. Your child's doctor may choose to first prescribe a different medication that does not have these risks.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Always store the orally disintegrating tablets in their sealed package, and use them immediately after opening the package.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include:

- drowsiness
- slurred speech
- agitation
- fast heartbeat
- sudden movements that you cannot control
- coma (loss of consciousness for a period of time)

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to olanzapine.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Zyprexa<sup>®</sup>
- Zyprexa<sup>®</sup> Zydys

## Brand names of combination products

- Symbyax<sup>®</sup> (containing Fluoxetine, Olanzapine )

Last Revised - 01/15/2022

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Page last updated: 25 March 2022