

ARTWORK APPROVAL REPORT

Product Information

Request Number :: AW-IL-19542

Request Type	Spec and Artwork Change	Component	Medication Guide
Customer	NA	Location	FTO Unit 3-2003
Product	Olanzapine OD	Pack Size	NA
Market	US	Material Description	MGD OLANZAPINE ODTabUSP5/10/15/20mgUSR6
Long Descriptor	Medication Guide Olanzapine OD 5/10/15/20mg Tablets US R6	Item Code	150101713
Material Type	Printed	Dosage Form	Tablets

E-Signature History

User Name	Role(Activity Name)	Status	DateTime(GM T)
Salkapuram Sathish Kumar	PD Upload	Submit	Mar 11 2025 11:11AM
Harinarayana A	PD Head Approval	Approve	Mar 15 2025 7:50AM
P Ravinder	RA Review	Approve	Mar 25 2025 11:51AM
Siva Prasad Jammula	QA for Implementation Date and Approval	Approve	Mar 28 2025 10:40AM

Medication Guide
Olanzapine Orally Disintegrating Tablets, USP
(oh lan' za peen)

Read the Medication Guide that comes with olanzapine orally disintegrating tablets before you start taking them 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 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 olanzapineorally disintegrating tablets?

Olanzapine orally disintegrating tablets are 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 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 tablet 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.
 - o 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-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 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 non-prescription 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.

How should I take olanzapine orally disintegrating tablets?

- Take olanzapine orally disintegrating tablets exactly as prescribed. Your doctor may need to change (adjust) the dose of olanzapine orally disintegrating tablets until it is right for you.
- If you miss a dose of olanzapine orally disintegrating 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 orally disintegrating tablets at the same time.
- **To prevent serious side effects, do not stop taking olanzapine orally disintegrating tablets suddenly. If you need to stop taking olanzapine orally disintegrating tablets, your doctor can tell you how to safely stop taking it.**
- **If you take too much olanzapine orally disintegrating tablets, call your doctor or poison control center at 1-800-222-1222 right away, or get emergency treatment.**
- Olanzapine orally disintegrating tablets can be taken with or without food.
- Olanzapine orally disintegrating tablets are usually taken one time each day.
- Take olanzapine orally disintegrating tablets 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.
- Call your doctor if you do not think you are getting better or have any concerns about your condition while taking olanzapine orally disintegrating tablets.

What should I avoid while taking olanzapine orally disintegrating tablets?

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

What are the possible side effects of olanzapine orally disintegrating tablets?

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

- **See “What is the most important information I should know about olanzapine orally disintegrating 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 orally disintegrating 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 orally disintegrating 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. 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 orally disintegrating tablets. It may also start after you stop taking olanzapine orally disintegrating 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 orally disintegrating 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 orally disintegrating 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 orally disintegrating 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 orally disintegrating tablets?

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

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

General information about olanzapine orally disintegrating tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use olanzapine orally disintegrating tablets for a condition for which it was not prescribed. Do not give olanzapine orally disintegrating 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 orally disintegrating tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about olanzapine orally disintegrating tablets that was written for healthcare professionals. For more information about olanzapine orally disintegrating tablets call 1-888-375-3784.

What are the ingredients in olanzapine orally disintegrating tablets?

Active ingredient: olanzapine

Orally Disintegrating Tablets — aspartame, colloidal silicon dioxide, crospovidone, magnesium stearate, mannitol, microcrystalline cellulose and guar gum (Avicel CE-15), microcrystalline cellulose (Avicel PH 101), microcrystalline cellulose (Avicel PH 112), pregelatinized starch and sodium lauryl sulphate.

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

Rx Only

Manufactured by:
Dr. Reddy’s Laboratories Limited
Bachupally - 500 090 INDIA

Revised: 03/2025

Dr.Reddy’s

150101713



Product Name: Olanzapine OD Tablets	Component: MG
Material Code: 150101713	Supersedes: 150084611
Open size: 300 x 500 mm	Folded Size: 125 x 75 mm
Barcode: NA	Bar code (%):
Date: 26-02-2025	Version: 00
Printing Colours: Black	Prepared by: Shiva Ram