

JUBREXA ODT

Olanzapine Ph. Eur. 5mg Orodispersable Tablet;

Olanzapine Ph. Eur. 10mg Orodispersable Tablet

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1. What Jubrex ODT tablet is used for

Jubrex ODT is used for acute and maintenance treatment for schizophrenia, a mental illness with symptoms such as hearing, seeing, or sensing things which are not there, mistaken beliefs, unusual suspiciousness and becoming withdrawn.

2. How Jubrex ODT tablet works

Jubrex ODT is an antipsychotic, antimanic, and mood stabilising agent which helps to correct chemical imbalances in the brain which may cause mental illness.

3. Before you take Jubrex ODT Tablets

When you must not use it

- if you are allergic (hypersensitive) to olanzapine or any of the other ingredients of Jubrex ODT.

An allergic reaction may be recognized as a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor.
- if you have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure in the eye).

Before you start to take it

Tell your doctor if you have or have had any medical conditions

or illnesses especially as following:

- Prostate problem (which cause difficulty in urination)
- Diabetes mellitus
- Hyperglycaemia(excess glucose in bloodstream, often associated with diabetes mellitus)
- Liver or kidney disease
- Blocked intestine (paralytic ileus)
- Blood disorder
- Seizures
- Parkinson's disease
- Stroke or mini stroke (temporary symptoms of stroke)
- Heart disease
- Dementia

Pregnancy and breastfeeding

- Tell your doctor if you are pregnant or breastfeeding, think that you may be pregnant or planning to become pregnant. Do not take Jubrex ODT until you and your doctor have discussed the risks and benefits involved.
- Do not use this medicine if you are breastfeeding as Olanzapine was excreted in breast milk.
- The following symptoms may occur in newborn babies, of mothers that have used Olanzapine in the last trimester (last three months of pregnancy); agitation, muscle stiffness and/ or weakness, sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these symptoms, you may need to contact your doctor immediately.

Olanzapine contains aspartame

- Patients who cannot take phenylalanine should note that Olanzapine tablets contain aspartame, which is a source of phenylalanine. Maybe harmful for people with

phenylketonuria.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines including medicines obtained without prescription.

Talk to your doctor or pharmacist if you are taking:

- Carbamazepine (used to control fits)
- Fluvoxamine (used to treat depression)
- Activated charcoal
- Medicines for Parkinson's disease

Other medicines not listed above may also interact with Olanzapine. Please consult your doctor or pharmacist for more information.

4. How to use Jubrex ODT tablets

How much to use

Always take Jubrex ODT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many Jubrex ODT tablets to take and how long you should continue to take them. The daily dose of Jubrex ODT is between 5 and 20 mg. Consult your doctor if your symptoms return but do not stop taking Jubrex ODT unless your doctor tells you to.
You should take your Jubrex ODT tablets once a day following the advice of your doctor.

Try to take your tablets at the same time each day. It does not matter whether you take them with or without food. Jubrex ODT tablets are for oral use.

Jubrex ODT break easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up.

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Instructions how to take the tablets out of the blister:

1. Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
2. Carefully peel off the backing.
3. Gently push the tablet out.
4. Put the tablet in your mouth. It will dissolve directly in your mouth, so that it can be easily swallowed.

You can also place the tablet in a full glass or cup of water and stir. Drink it straight away.

When to use it

Jubrex ODT can be given without regard for meals, as absorption is not affected by food. Gradual tapering of the dose should be considered when discontinuing Jubrex ODT.

How long to use it

Your doctor or pharmacist will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

If you forget to use it

Take your tablets as soon as you remember. Do not take two doses in one day.

If you use too much (overdose)

Do not stop taking your tablets just because you feel better. It is important that you carry on taking Jubrex ODT for as long as your doctor tells you.

If you suddenly stop taking Jubrex ODT, symptoms such as sweating, unable to sleep, tremor, anxiety or nausea and vomiting might occur.

Your doctor may suggest you to reduce the dose gradually before stopping treatment.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

5. While you are using

Jubrex ODT

Things you must do

Tell all doctors, dentists and pharmacists that are treating you that you are taking Jubrex ODT. Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not drink any alcohol if you have been given Jubrex ODT as Jubrex ODT and alcohol together may make you feel drowsy.

Driving and using machine:

There is a risk of feeling drowsy when you are given Jubrex ODT. If this happens do not drive or operate any tools or machines. Tell your doctor.

Things to be careful of

- The use of Jubrex ODT in elderly patients with dementia is not recommended as it may have serious side effects.
- Blood pressure need to be measured periodically in people over 65 years as postural low blood pressure was frequently observed in elderly.
- patients with diabetes mellitus who have started on medicines like Jubrex ODT should be monitored for worsening of glucose control.

6. Side Effects

Like all medicines, Jubrex ODT can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of these symptoms:

- Allergic reaction (e.g. swelling in the mouth and throat, itching, rash).
- Combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness.
- Unusual movement (especially of the face or tongue).
- Blood clots in the veins, especially in the legs. Symptoms include swelling, pain, and redness in the leg which may travel through

blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.

Tell your doctor if any of the below side effects starts bothering you:

Very common side effects:

- Weight gain.
- Sleepiness.
- Increases in the levels of prolactin in the blood.

Common side effects:

- Changes in the levels of some blood cells and circulating fats.
- Increases in the level of sugars in the blood and urine.
- Feeling more hungry.
- Dizziness.
- Restlessness.
- Tremor.
- Muscle stiffness or spasm (including eye movements).
- Problems with speech.
- Constipation.
- Dry mouth.
- Rash.
- Loss of strength.
- Extreme tiredness.
- Water retention leading to swelling of the hands, ankles or feet.
- In the early stages of treatment, some people may feel dizzy or faint (with a slow heart rate), especially when getting up from a lying or sitting position. This will usually pass on its own but if it does not, tell your doctor.
- Sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

Very Rare: Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported with Olanzapine exposure. DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen on blood tests and an increase in a type of white

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blood cells (eosinophilia).
Discontinue Jubrex ODT if
DRESS is suspected.

If you notice any side effects not listed in this leaflet, please tell your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

7. Storage and Disposal of Jubrex ODT tablet

Store below 30°C. Keep out of the reach and sight of children.

Jubrex ODT should be stored in its original pack in order to protect from light and moisture.

Do not use Jubrex ODT after the expiry date, which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

What it looks like

Jubrex ODT 5 mg Tablet

Yellow coloured, round, flat face beveled edge tablets with characteristic flavour, debossed with “D5” on one side and “CO” on other side.

Jubrex ODT 10 mg Tablet

Yellow coloured, round, flat face beveled edge tablets with characteristic flavour, debossed with “D10” on one side and “CO” on other side.

Ingredients

Active ingredient:
Olanzapine

Excipients:
Mannitol, Low Substituted Hydroxypropyl Cellulose,

Aspartame, Strawberry Flavor, Silica colloidal anhydrous, Magnesium Stearate.

MAL Numbers

Jubrex ODT 5 mg Tablet:

MAL17107012AZ

Jubrex ODT 10 mg Tablet

MAL17107013AZ

9. Manufacturer

Jubilant Life Sciences Ltd.,
Village Sikandarpur Bhainswal,
Roorkee- Dehradun Highway,
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Product Registration Holder

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10. Date of Revision

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