

PACKAGE LEAFLET: INFORMATION FOR THE USER
Olanzapine 2.5, 5, 7.5, 10, 15 and 20 mg film-coated Tablets
Olanzapine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.



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1. What Olanzapine is and what it is used for
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1. WHAT OLANZAPINE IS AND WHAT IT IS USED FOR

Olanzapine belongs to a group of medicines called antipsychotics.

Olanzapine is used to treat schizophrenia, a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense.

Olanzapine is used to treat moderate to severe manic episodes, with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. It is also a mood stabiliser that prevents further occurrences of the disabling high and low (depressed) extremes of mood associated with bipolar disorder.

2. BEFORE YOU TAKE OLANZAPINE

Do not take Olanzapine

- if you are allergic (hypersensitive) to olanzapine or any of the other ingredients of Olanzapine Tablets (see Section 6. Further Information). An allergic reaction may be recognised 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).

Take special care with Olanzapine

- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given Olanzapine Tablets tell your doctor.
- Very rarely, medicines of this type cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor at once.
- If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- Weight gain has been seen in patients taking Olanzapine. You and your doctor should check your weight regularly.
- High blood pressure and high levels of fat (triglycerides and cholesterol) have been seen in patients taking Olanzapine. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking Olanzapine and regularly during treatment.
- The use of Olanzapine in elderly patients with dementia is not recommended as it may have serious side effects.

If you suffer from any of the following illnesses tell your doctor as soon as possible:

- Diabetes
- Heart disease
- Liver or kidney disease
- Parkinson's disease
- Epilepsy
- Prostate problems
- A blocked intestine (Paralytic ileus)
- Blood disorders
- Stroke or "mini" stroke (temporary symptoms of stroke)

If you suffer from dementia, you or your carer/relative should tell your doctor if you have ever had a stroke or "mini" stroke.

As a routine precaution, if you are over 65 years your blood pressure may be monitored by your doctor.

Olanzapine is not for patients who are under 18 years.

Taking other medicines

Only take other medicines while you are taking Olanzapine Tablets if your doctor tells you that you can. You might feel drowsy if Olanzapine is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

You should tell your doctor if you are taking fluvoxamine (an antidepressant) or ciprofloxacin (an antibiotic), as it may be necessary to change your dose of Olanzapine Tablets.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially tell your doctor if you are taking medicines for Parkinson's disease.

Taking Olanzapine with food and drink

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

Pregnancy and breast-feeding

Tell your doctor as soon as possible if you are pregnant or think you may be pregnant. You should not take this medicine when pregnant, unless you have discussed this with your doctor. You should not be given this medicine when breast-feeding, as small amounts of Olanzapine can pass into breast milk.

The following symptoms may occur in newborn babies, of mothers that have used Olanzapine Tablets in the last trimester (last three months of their pregnancy): shaking, 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.

Driving and using machines

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

Important information about some of the ingredients of Olanzapine Tablets

Olanzapine Tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE OLANZAPINE

Always take Olanzapine Tablets 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 Olanzapine Tablets to take, and how long you should continue to take them. The daily dose of olanzapine is between 5 and 20 mg. Consult your doctor if your symptoms return but do not stop taking Olanzapine Tablets unless your doctor tells you to.

You should take your Olanzapine Tablet once a day following the advice of your doctor. Try to take your tablet at the same time each day. It does not matter whether you take them with or without food. Olanzapine Tablets are for oral use. You should swallow the tablet whole with water.

If you take more Olanzapine than you should

Patients who have taken more Olanzapine Tablets than they should, have experienced the following symptoms: rapid beating of the heart, agitation/aggressiveness, problems with speech, unusual movements (especially of the face or tongue) and reduced level of consciousness.

Other symptoms may be: acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness, slowing of the breathing rate, aspiration, high blood pressure or low blood pressure, abnormal rhythms of the heart.

Contact your doctor or hospital **straight away**. Show the doctor your pack of tablets.

If you forget to take Olanzapine

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

If you stop taking Olanzapine

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

If you suddenly stop taking Olanzapine, 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.

4. POSSIBLE SIDE EFFECTS

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

Some side effects can be serious and you should immediately contact your doctor or pharmacist if you notice any of the following symptoms:

- Changes in the levels of some blood cells and circulating fats. These may not show any specific signs or symptoms and will only be confirmed following a blood test. Possible signs of changes in blood cells can include wheezing, rashes, feeling unwell, tiredness, weakness, bruising or bleeding easily.
- Rash, changes in blood pressure, swelling and increased fluid in tissues, an increased heart rate, difficulty with breathing and collapse. These may be signs of a severe allergic reaction.
- Combination of fever, faster breathing, sweating, muscle stiffness, drowsiness or sleepiness, and confusion or agitation, or if you experience jerky muscle movement which you can't control. These may be the symptoms of a serious condition known as neuroleptic malignant syndrome.
- Blood clots such as deep venous thrombosis of the leg (symptoms include swelling, pain and redness in the leg) or blood clot of the lungs causing chest pain and difficulty in breathing.
- Liver disease appearing as yellowing of the skin and white parts of the eyes.
- Muscle disease presenting as unexplained aches and pains.

Other side effects that have been reported include:

Very common side effects: affect 1 user in 10

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

Common side effects: affect 1 to 10 users in 100

- Increases in the level of sugars in the blood and urine.
- Feeling more hungry.
- Dizziness.
- Restlessness.
- Tremor.
- Problems with speech.
- Unusual movement (especially of the face or tongue).
- 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.

Uncommon side effects: affect 1 to 10 users in 1,000

- Slow heart rate.
- Make you sensitive to sunlight.
- Urinary incontinence.
- Hair loss.
- Absence or decrease in menstrual periods.
- Changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.

Other possible side effects: frequency cannot be estimated from the available data.

- Diabetes or the worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma.
- Lowering of normal body temperature.
- Seizures, usually associated with a history of seizures (epilepsy).
- Combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness.
- Spasms of the muscle of the eye causing rolling movement of the eye.
- Abnormal rhythms of the heart.
- Sudden unexplained death.
- Inflammation of the pancreas causing severe stomach pain, fever and sickness.
- Liver disease appearing as yellowing of the skin and white parts of the eyes.
- Difficulty in passing urine.
- Prolonged and/or painful erection.

While taking olanzapine, elderly patients with dementia may suffer from stroke, pneumonia, urinary incontinence, falls, extreme tiredness, visual hallucinations, a rise in body temperature, redness of the skin and have trouble walking. Some fatal cases have been reported in this particular group of patients.

In patients with Parkinson's disease Olanzapine may worsen the symptoms.

Rarely women taking medicines of this type for a long time have started to secrete milk and have missed periods or had irregular periods. If this persists tell your doctor.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE OLANZAPINE

Keep out of the reach and sight of children.

Do not use Olanzapine after the expiry date, which is stated on the carton. Do not store above 25°C.

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.

6. FURTHER INFORMATION

What Olanzapine Tablets contain:

The active substance is olanzapine. Each tablet contains 2.5mg, 5 mg, 7.5 mg, 10 mg, 15 mg or 20 mg of olanzapine.

The other ingredients are lactose monohydrate, microcrystalline cellulose, crospovidone, hydroxypropyl cellulose, magnesium stearate. The tablet coating contains hypromellose, titanium dioxide (E171), macrogol 400. The tablet coating for 5, 7.5 and 10 mg tablets also contains indigo carmine aluminium lake (E132).

What Olanzapine Tablets look like and contents of the pack

Olanzapine 2.5 mg film-coated tablets are white, oval, biconvex film-coated tablets, debossed "OLZ" on one side and "2.5" on other side.
Olanzapine 5 mg film-coated tablets are blue, oval, biconvex film-coated tablets, debossed "OLZ" on one side and "5" on other side.
Olanzapine 7.5 mg film-coated tablets are blue, oval, biconvex film-coated tablets, debossed "OLZ" on one side and "7.5" on other side.
Olanzapine 10 mg film-coated tablets are blue, oval, biconvex film-coated tablets, debossed "OLZ" on one side and "10" on other side.
Olanzapine 15 mg film-coated tablets are white, round, biconvex film-coated tablets, debossed "OLZ" on one side and "15" on other side.
Olanzapine 20 mg film-coated tablets are white, oval, biconvex film-coated tablets, debossed "OLZ" on one side and "20" on other side.
Cartons contain 7, 14, 28, 35, 56, 70, 98 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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