

Package leaflet: Information for the user

Olanzapine 5 mg orodispersible tablets
Olanzapine 10 mg orodispersible tablets
Olanzapine 15 mg orodispersible tablets
Olanzapine 20 mg orodispersible tablets

Olanzapine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Olanzapine tablets are and what they are used for
2. What you need to know before you take Olanzapine tablets
3. How to take Olanzapine tablets
4. Possible side effects
5. How to store Olanzapine tablets
6. Contents of the pack and other information

1. What Olanzapine tablets are and what they are used for

Olanzapine tablets contain the active substance olanzapine. Olanzapine tablets belongs to a group of medicines called antipsychotics and are used to treat the following conditions:

- 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.
- Moderate to severe manic episodes, a condition with symptoms of excitement or euphoria.

Olanzapine tablets have been shown to prevent recurrence of these symptoms in patients with bipolar disorder whose manic episode has responded to olanzapine treatment.

2. What you need to know before you take Olanzapine tablets

Do not take Olanzapine tablets

- If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine (listed in section 6). 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).

Warnings and precautions

Talk to your doctor or pharmacist before you take Olanzapine tablets.

- The use of Olanzapine tablets in elderly patients with dementia is not recommended as it may have serious side effects.
- 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. Weight gain has been seen in patients taking Olanzapine tablets. You and your doctor should check your weight regularly. Consider referral to a dietician or help with a diet plan if necessary.
- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in patients taking Olanzapine tablets. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking Olanzapine tablets and regularly during treatment.
- Tell your doctor if you or someone else in your family has a history of blood clots, as medicines like these have been associated with the formation of blood clots.

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

- Stroke or “mini” stroke (temporary symptoms of stroke)
- Parkinson’s disease
- Prostate problems
- A blocked intestine (Paralytic ileus)
- Liver or kidney disease
- Blood disorders
- Heart disease
- Diabetes
- Seizures
- If you know that you may have a salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)

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.

Children and adolescents

Olanzapine tablets are not for patients who are under 18 years.

Other medicines and Olanzapine tablets

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

Tell your doctor if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking:

- medicines for Parkinson’s disease.
- carbamazepine (an anti-epileptic and mood stabiliser), fluvoxamine (an antidepressant) or ciprofloxacin (an antibiotic) - it may be necessary to change your Olanzapine tablets dose.

Olanzapine tablets with alcohol

Do not drink any alcohol if you have been given Olanzapine tablets as together with alcohol it may make you feel drowsy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not be given this medicine when breast-feeding, as small amounts of Olanzapine tablets 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.

Olanzapine tablets contain aspartame

This medicine contains up to 2.8 mg (5 mg strength), 5.6 mg (10 mg strength) , 8.4 mg (15 mg strength) and 11.2 mg (20 mg strength) aspartame in each tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Olanzapine tablets

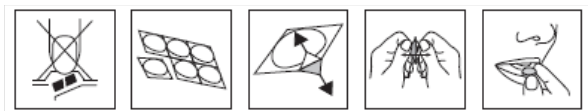
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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 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. Olanzapine orodispersible tablets are for oral use.

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

1. Keep your hands dry. Do not push the tablet out of the pocket
2. Separate one blister cell from the strip
3. Carefully peel off the backing
4. Take the tablet out of the pocket



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, orange juice, apple juice or milk, and stir. With some drinks, the mixture may change colour and possibly become cloudy. Drink it straight away.

If you take more Olanzapine tablets 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 if you experience any of the above symptoms. Show the doctor your pack of tablets.

If you forget to take Olanzapine tablets

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

If you stop taking Olanzapine tablets

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

If you suddenly stop taking Olanzapine tablets, symptoms such as sweating, inability 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor immediately if you have:

- unusual movement (a common side effect that may affect up to 1 in 10 people) mainly of the face or tongue;
- blood clots in the veins (an uncommon side effect that may affect up to 1 in 100 people) 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;
- a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness (the frequency of this side effect cannot be estimated from the available data).

Very common side effects (may affect more than 1 in 10 people) include weight gain; sleepiness; and increases in levels of prolactin in the blood. 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.

Common side effects (may affect up to 1 in 10 people) include changes in the levels of some blood cells, circulating fats and early in treatment, temporary increases in liver enzymes ; increases in the level of sugars in the blood and urine; increases in levels of uric acid and creatine phosphokinase in the blood; feeling more hungry; dizziness; restlessness; tremor; unusual movements (dyskinesias); constipation; dry mouth; rash; loss of strength; extreme tiredness; water retention leading to swelling of the hands, ankles or feet; fever, joint pain and sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

Uncommon side effects (may affect up to 1 in 100 people) include hypersensitivity (e.g. swelling in the mouth and throat, itching, rash); diabetes or the worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma; seizures, usually associated with a history of seizures (epilepsy); muscle stiffness or spasm (including eye movements); restless legs syndrome; problems with speech; stuttering; slow heart rate; sensitivity to sunlight; bleeding from the nose; abdominal distension; drooling; memory loss or forgetfulness; urinary incontinence; lack of ability to urinate; hair loss; absence or decrease in menstrual periods; and changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.

Rare side effects (may affect up to 1 in 1000 people) include lowering of normal body temperature;

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; muscle disease presenting as unexplained aches and pains; and prolonged and/or painful erection.

Very rare side effects (may affect up to 1 in 10,000 people) include serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). 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 in blood tests and an increase in a type of white blood cell (eosinophilia).

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 tablets may worsen the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Olanzapine tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton.

Olanzapine tablets should be stored in its original pack in order to protect from light and moisture. Olanzapine tablets do not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Olanzapine tablets contain

- The active substance is olanzapine. Each Olanzapine orodispersible tablet contains either 5 mg, 10 mg, 15 mg or 20 mg of the active substance. The exact amount is shown on your Olanzapine tablets pack.
- The other ingredients are
 - magnesium stearate, L-Methionine, colloidal anhydrous silica, hydroxypropyl cellulose (low substituted), crospovidone (Type B), aspartame, microcrystalline cellulose, guar gum, magnesium carbonate heavy and orange flavour.

What Olanzapine tablets looks like and contents of the pack

Olanzapine 5 mg orodispersible tablet is a round, biconvex, yellow orodispersible tablet, 6 mm in diameter and marked with "O" on one side.

Olanzapine 10 mg orodispersible tablet is a round biconvex, yellow orodispersible tablet 8 mm in diameter and marked with "O1" on one side.

Olanzapine 15 mg orodispersible tablet is a round, biconvex, yellow orodispersible tablet, 9 mm in diameter and marked with “O2” on one side.

Olanzapine 20 mg orodispersible tablet is a round, biconvex, yellow orodispersible tablet, 10 mm in diameter and marked with “O3” on one side. Orodispersible tablet is the technical name for a tablet which dissolves directly in your mouth, so that it can be easily swallowed.

Pack sizes:

Push-through blister packs: 28, 35, 56 and 70 orodispersible tablets.

Peel-to open blister packs: 28, 35, 56 and 70 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Actavis hf.
Reykjavíkurvegi 78
IS-220 Hafnarfjörður
Iceland

Actavis Ltd.
B16, Bulebel Industrial Estate
Zejtun ZTN 08
Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Olanzapine 5 mg / 10 mg / 15 mg / 20 mg Orodispersible Tablets
UK	Olanzapine 5 mg / 10 mg / 15 mg / 20 mg Orodispersible Tablets

This leaflet was last revised in May 2021