

APO-Olanzapine Tablets

Olanzapine

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about olanzapine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Olanzapine belongs to a group of medicines called antipsychotics. Olanzapine is used:

- to treat symptoms of schizophrenia and related psychoses
- alone, or in combination with lithium or valproate, for the short-term treatment of acute manic episodes associated with Bipolar I Disorder
- as a mood stabiliser that prevents further occurrences of the disabling high and low extremes of mood associated Bipolar I Disorder

How it works

Olanzapine helps to correct chemical imbalances in the brain, which may cause mental illness.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend using olanzapine in children under the age of 18 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- olanzapine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin;

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- tumour of the pituitary gland
- chest infection e.g. pneumonia
- bone marrow depression or conditions of the blood with a reduced number of white or red blood cells
- disease of the blood vessels of the brain, including stroke
- Parkinson's Disease or dementia, or problems swallowing
- prostate problems
- kidney or liver disease
- high blood pressure
- high blood sugar, diabetes or a family history of diabetes
- high cholesterol levels in your blood
- breast cancer or a family history of breast cancer
- paralytic ileus, a condition where the small bowel does not work properly
- epilepsy (seizures or fits)
- narrow-angled glaucoma, a condition in which there is usually a build-up of fluid in the eye
- heart disease, including irregular heart rhythm
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions
- tardive dyskinesia, a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs
- sleep apnoea, a sleep disorder where a person has pauses in breathing or periods of shallow breathing during sleep.
- lactose intolerance - these tablets contain lactose

Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding

Olanzapine is not recommended for use during pregnancy or breastfeeding.

Tell your doctor if you will be in a hot environment or do a lot of vigorous exercise. Olanzapine may make you sweat less, causing your body to overheat.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interact with olanzapine. These include:

- medicines used to treat a fast or irregular heart beat (arrhythmia)
- medicines taken for anxiety or to help you sleep
- fluvoxamine and other medicines taken for depression

- carbamazepine, used for mood stabilisation and epilepsy
- other centrally acting medicines (e.g. tranquillisers)
- ciprofloxacin, used to treat bacterial infections
- medicines that lower blood pressure, including diuretics which help remove excess water from the body
- medicines used for Parkinson's disease
- medicines which may have anticholinergic activity
- medicines that can change the heart's electrical activity or make it more likely to change

Smoking may affect olanzapine or may affect how it works.

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Other medicines not listed above may also interact with olanzapine.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take, depending on your condition and if you are taking other medicines.

The dose your doctor will prescribe for you will usually be in the range of 5 mg to 20 mg taken once a day.

Your doctor may increase or decrease your dose to find the appropriate dose for your condition.

A lower starting dose may be prescribed for elderly patients over the age of 65 years

How to take it

Swallow the tablets whole with a glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It doesn't matter if you take this medicine with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Do not stop taking olanzapine just because you feel better. It is important that you do not stop taking olanzapine unless your doctor tells you to.

Make sure you have enough medicine to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you have taken too much olanzapine, the most common signs are fast heartbeat, agitation, aggression, difficulty speaking, uncontrollable movements and sleepiness (sedation).

While you are using this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell all doctors, dentists and pharmacists who are treating you that you are taking olanzapine.

If you become pregnant or start breastfeeding while taking this medicine, tell your doctor immediately.

Talk to your doctor or mental health professional if you have thoughts or talk about death or suicide; or thoughts or talk about self-harm or doing harm to others.

These may be signs of changes or worsening in your mental illness.

Tell your doctor if you are female and your monthly periods are absent for six months or more.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do tests to make sure the medicine is working and to prevent side effects.

Your doctor should monitor you particularly closely in the first weeks that you start taking this medicine.

Your doctor should also monitor your weight while you are taking olanzapine.

Patients with diabetes or who have a higher chance of developing diabetes should have their blood sugar checked often.

If you are over 65, your doctor may measure your blood pressure from time to time.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how olanzapine affects you.

Olanzapine may cause drowsiness in some people.

Be careful when drinking alcohol while taking olanzapine.

The effects of alcohol could be made worse while taking olanzapine.

Wear sunscreen and protective clothing if outside, as olanzapine may make your skin more sensitive to the sun.

Make sure you keep cool in hot weather and keep warm in cool weather.

Olanzapine may affect the way your body reacts to temperature changes.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking olanzapine.

This medicine helps most people with mood disorders, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following:

- drowsiness
- unusual tiredness or weakness
- restlessness or difficulty sitting still
- increased appetite, weight gain
- constipation or bloating
- dry mouth or excessive saliva
- swelling of your hands, feet and ankles due to excess fluids
- joint pain
- nose bleeds
- aching joints
- dizziness, confusion or forgetfulness
- sleepwalking
- sleep eating

Some people may feel dizzy in the early stages of treatment, especially when getting up from a lying or sitting position. This side effect usually passes after taking olanzapine for a few days.

Tell your doctor as soon as possible if you notice any of the following.

- symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) which occur more quickly than normal
- rash
- changes in sexual functioning or sex drive in men or women
- prolonged and/or painful erection
- unusual secretion of breast milk
- breast enlargement in men or women
- passing large amounts of urine, excessive thirst, having a dry mouth and skin and weakness (signs of high sugar levels in the blood)
- profuse sweating, nausea or vomiting (possible reaction following abrupt discontinuation)
- absence of menstrual periods, changes in the regularity of menstrual periods
- difficulty initiating or controlling urination
- unusual hair loss or thinning
- unpleasant or uncomfortable sensations in the legs and an irresistible urge to move them
- stuttering or speech difficulty

- sleep apnoea

The above list includes serious side effects and you may need medical attention.

If you experience any of the following, contact your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, or other parts of the body; rash, itching or hives on the skin (signs of an allergic reaction)
- fever, rash, facial swelling, enlarged lymph nodes, problems with the kidney and liver (signs of DRESS allergy)
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- seizures, fits or convulsions
- diabetic coma
- nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and/or eyes
- pain in the upper stomach area (pancreas inflammation)
- severe upper stomach pain often with nausea and vomiting
- worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to the arms and legs
- sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions
- sharp chest pain, coughing of blood, sudden shortness of breath
- fainting or passing out
- pain or tenderness in the calf muscle area
- muscle pain, muscle weakness and brown urine
- fast, slow or irregular heartbeat
- dark coloured urine
- thoughts of suicide or attempting suicide or self-harm

The above list includes very serious side effects and you may need urgent medical attention or hospitalisation.

Some side effects, such as changes to liver function, cholesterol or triglycerides can occur. These can only be found when your doctor does tests from time to time to check your progress.

Elderly patients with dementia-related psychosis may notice the following side effects:

- unusual manner of walking
- falls
- pneumonia
- inability to retain urine

Some patients with Parkinson's disease may hallucinate (see, feel or hear things that are not there) or develop worsening symptoms of Parkinson's disease.

Patients with bipolar mania taking olanzapine in combination with lithium or valproate may notice the following additional side effects:

- tremors
- speech disorder

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Storage and Disposal

Storage

Keep your medicine in its pack until it is time to take it.

If you take your medicine out of its pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product description

What it looks like

Light yellow to yellow, slightly mottled, round, biconvex tablets, plain on one side.

- 2.5mg tablet: Debossed with 'O4' on one side. AUST R 303714
- 5mg tablet: Debossed with 'O5' on one side. AUST R 303715
- 7.5mg tablet: Debossed with 'O6' on one side. AUST R 303716
- 10mg tablet: Debossed with 'O7' on one side. AUST R 303717

Available in blister packs of 28 tablets.

Not all strengths may be available.

Ingredients

Each tablet contains either 2.5mg, 5mg, 7.5mg or 10mg of olanzapine as the active ingredient.

It also contains the following:

- lactose
- microcrystalline cellulose
- magnesium stearate
- hyprolose

This medicine contains sugars (as lactose).

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
CREMORNE VIC 3121
www.arrotex.com.au

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