

APO-Olanzapine Film Coated Tablets

Contains the active ingredient 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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Olanzapine. It contains the active ingredient olanzapine.

It 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 also a mood stabiliser that prevents further occurrences of the disabling high and low (depressed) extremes of mood associated Bipolar I Disorder.

Schizophrenia is a mental illness with disturbances in thinking, feelings and behaviour. Bipolar I Disorder is a mental illness 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.

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.

How it works

Olanzapine belongs to a group of medicines called antipsychotics. It helps to correct chemical imbalances in the brain, which may cause mental illness.

Olanzapine may be used together with other medicines such as lithium or valproate.

There is no evidence that this medicine is addictive.

Use in children

Olanzapine is not recommended for use 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 are hypersensitive to, or have had an allergic reaction to olanzapine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, 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; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - tumour of the pituitary gland (a small gland at the base of the brain)
 - 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 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.

3. You are currently pregnant or you plan to become pregnant.

Like most antipsychotic medicines, olanzapine is not recommended for use during pregnancy.

4. You are currently breastfeeding or you plan to breastfeed.

It is recommended that you do not breastfeed while taking olanzapine.

5. You suffer from lactose intolerance.
APO-Olanzapine film coated tablets contain lactose.
6. 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
7. You have recently been vaccinated or plan to get a vaccination.
8. You are planning to have surgery.
9. You are currently receiving or are planning to receive dental treatment.

10. You are taking or are planning to take any other medicines; this includes vitamins and supplements that are available 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, a medicine used for mood stabilisation and to treat epilepsy
- other centrally acting medicines (e.g. tranquilisers)
- ciprofloxacin, a medicine 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.

If you are taking any of these you may need a different dose 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 carefully. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

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

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

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

How to take it

Swallow olanzapine film coated tablets whole, with a glass of water.

When to take it

Olanzapine film coated tablets should be taken once a day as advised by your doctor. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

Olanzapine film coated tablets can be taken with or without food.

How long to take it for

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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

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 sedation.

While you are taking this medicine

Things you must do

It is important that you remember to take olanzapine daily and at the same dose prescribed by your doctor.

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.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or are going into hospital.

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. Go to your doctor regularly for a check-up.

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.

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

Things you must not do

Do not:

- Stop taking your medicine, or change the dosage, without first checking with your doctor.
- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor tells you to

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

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- drowsiness
- unusual tiredness or weakness
- joint pain
- restlessness or difficulty sitting still
- increased appetite, weight gain
- constipation
- dry mouth

- nose bleeds
- swelling of your hands, feet and ankles due to excess fluids
- dizziness

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.

These may be serious side effects and you may need medical attention.

- 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
- symptoms of high sugar levels in the blood (including passing large amounts of urine, excessive thirst, having a dry mouth and skin and weakness). These may indicate the onset or worsening of diabetes.
- reaction following abrupt discontinuation (profuse sweating, nausea or vomiting)
- absence of menstrual periods and 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.

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

These are very serious side effects and you may need urgent medical attention or hospitalisation.

- 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-unconsciousness caused by extreme blood sugar levels
- yellowing of the skin and/or eyes
- nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and/or eyes
- inflammation of the pancreas (pain in the upper stomach area)
- 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, or sudden shortness of breath
- fainting or passing out
- pain/tenderness in the calf muscle area
- fast, slow or irregular heartbeat
- dark coloured urine
- thoughts of suicide or attempting suicide or self-harm.

Also, 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 (urinary incontinence).

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.

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

Allergic reactions

If you think you are having an allergic reaction to olanzapine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

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

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

Keep your medicine in a cool dry place where the temperature will stay below 25°C and protect from light.

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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Olanzapine looks like

APO-Olanzapine film coated tablets are available in the following strengths:

- 2.5 mg tablet: white, round, biconvex film-coated tablet. Engraved "APO" on one side, "OLA" over "2.5" on the other side.

- 5 mg tablet: white, round, biconvex film-coated tablet. Engraved "APO" on one side, "OLA" over "5" on the other side.
- 7.5 mg tablet: white, round, biconvex film-coated tablet. Engraved "APO" on one side, "OLA" over "7.5" on the other side.
- 10 mg tablet: white, round, biconvex film-coated tablet. Engraved "APO" on one side, "OLA" over "10" on the other side.
- 15 mg tablet: light blue, elliptical, biconvex film-coated tablet. Engraved "APO" on one side, "OLA 15" on the other side.
- 20 mg tablet: light pink, elliptical, biconvex film-coated tablet. Engraved "APO" on one side, "OLA 20" on the other side.

They are available in blister packs of 28 tablets and bottles of 28, 100 and 500 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each APO-Olanzapine film coated tablets contain either 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg or 20 mg of olanzapine as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- microcrystalline cellulose
- maize starch
- magnesium stearate
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- indigo carmine aluminium lake (15 mg tablet only)
- iron oxide red (20 mg tablet only)
- iron oxide yellow (20 mg tablet only).

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Olanzapine 2.5 mg film coated tablets (blister pack):

AUST R 158979

APO-Olanzapine 2.5 mg film coated tablets (bottle): AUST R 158978

APO-Olanzapine 5 mg film coated tablets (blister pack):

AUST R 158981

APO-Olanzapine 5 mg film coated tablets (bottle): AUST R 158997

APO-Olanzapine 7.5 mg film coated tablets (blister pack):

AUST R 158987

APO-Olanzapine 7.5 mg film coated tablets (bottle): AUST R 158977

APO-Olanzapine 10 mg film coated tablets (blister pack):

AUST R 158970

APO-Olanzapine 10 mg film coated tablets (bottle): AUST R 159002

APO-Olanzapine 15 mg film coated tablets (blister pack):

AUST R 158969

APO-Olanzapine 15 mg film coated tablets (bottle): AUST R 158964

APO-Olanzapine 20 mg film coated tablets (blister pack):

AUST R 158976

APO-Olanzapine 20 mg film coated tablets (bottle): AUST R 158961

Sponsor

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Australia

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