

Apo-Olanzapine

olanzapine

2.5mg, 5mg, 7.5mg 10mg, 15mg and 20mg film coated tablets
and
5mg, 10mg, 15mg and 20mg orally disintegrating tablets

What is in this leaflet

Please read this leaflet carefully before you start using Apo-Olanzapine.

This leaflet answers some common questions about Apo-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 Apo-Olanzapine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Apo-Olanzapine is used for

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

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

Apo-Olanzapine is used:

- to treat symptoms of schizophrenia and related psychoses. Schizophrenia is a mental illness with disturbances in thinking, feelings and behaviour.
- alone or in combination with lithium or valproate is indicated 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 (depressed) extremes of mood associated with Bipolar I Disorder.

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.

Your doctor may have prescribed Apo-Olanzapine for another reason.

Ask your doctor if you have any questions about why Apo-Olanzapine has been prescribed for you.

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

Apo-Olanzapine is not recommended for use in children under the age of 18 years.

Before you use Apo-Olanzapine

When you must not use it

Do not use Apo-Olanzapine 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, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-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.**
If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start using Apo-Olanzapine, talk to your doctor.

Before you start to use it

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
- disease of the blood with a reduced number of white or red blood cells
- disease of the blood vessels of the brain, including stroke
- prostate problems
- kidney or liver disease
- high blood sugar, diabetes or a family history of diabetes
- 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)
- glaucoma, a condition in which there is usually a buildup 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.
- Parkinson's Disease or dementia, or problems swallowing
- high blood pressure
- high cholesterol levels in your blood

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

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.

Your doctor will discuss with you the risks and benefits of taking olanzapine when breast-feeding.

5. 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.

6. You suffer from lactose intolerance because Apo-Olanzapine film coated tablets contain lactose.

7. You are intolerant to Sulphur because Apo-Olanzapine film coated tablets contain a colourant that contains Sulphur.

- 8. You are intolerant to sucralose because Apo-Olanzapine orally disintegrating tablets contain sucralose.**
- 9. You are intolerant to mannitol because Apo-Olanzapine orally disintegrating tablets contain mannitol.**
- 10. You smoke.**
Smoking may affect Apo-Olanzapine or may affect how it works.
- 11. You are planning to have surgery or an anaesthetic.**
- 12. You are currently receiving or are planning to receive dental treatment.**

If you have not told your doctor about any of the above, tell them before you start using Apo-Olanzapine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Olanzapine.

Some medicines may interfere with Apo-Olanzapine. These include:

- medicines used to treat a fast or irregular heart beat (arrhythmia)
- medicines taken for anxiety or to help you sleep
- medicines taken for depression (e.g. fluoxetine, fluvoxamine)
- carbamazepine, a medicine used for mood stabilization and to treat epilepsy
- other centrally acting medicines (tranquillisers)
- 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 that can change the heart's electrical activity or make it more likely to change

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

Other medicines not listed above may also interact with Apo-Olanzapine.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Olanzapine.

How to use Apo-Olanzapine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

The label should be carefully read

How much to take

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

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.

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

How to take it

Apo-Olanzapine film coated tablets:

Swallow the tablet(s) with a glass of water.

Apo-Olanzapine orally disintegrating tablets:

Do not handle the orally disintegrating tablet with wet hands as the tablets break easily. Handle the tablets carefully.

Put the orally disintegrating tablet in your mouth. It will dissolve directly in your mouth, so it can be easily swallowed.

Or you can place the orally disintegrating tablet in a full glass of water or other suitable beverage (orange juice, apple juice, milk or coffee) and stir.

Drink it straight away.

With some drinks, the mixture may change colour and possibly become cloudy.

The orally disintegrating tablet should not be placed in cola drinks.

When to take it

Apo-Olanzapine should be taken once a day as advised by your doctor.

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

Apo-Olanzapine can be taken with or without food.

How long to take it

Do not stop taking Apo-Olanzapine just because you feel better. It is important that you continue taking your medicine for as long as your doctor tells you.

Your doctor will advise you when you can stop taking Apo-Olanzapine completely.

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.

While you are using Apo-Olanzapine

Things you must do

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

Immediately stop taking Apo-Olanzapine and check with your doctor if a skin rash or other allergic reaction occurs.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Apo-Olanzapine.

Take your medicine exactly as your doctor has prescribed.

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

Tell your doctor (immediately) if you become pregnant while you are taking it.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Apo-Olanzapine.

- Your doctor should monitor your weight while you are taking Apo-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 your doctor if you are female and your monthly periods are absent for six months or more.

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.

Always discuss with your doctor any problems or difficulties during or after taking Apo-Olanzapine.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Apo-Olanzapine to last weekends and holidays.

Things you must not do

Do not stop taking Apo-Olanzapine, or lower the dosage, even if you are feeling better, without checking with your doctor.

Do not give Apo-Olanzapine to anyone else, even if they have the same condition as you.

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

Do not take any other medicine while you are taking Apo-Olanzapine without first telling your doctor.

Do not take Apo-Olanzapine for a longer time than your doctor has prescribed.

Things to be careful of

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how Apo-Olanzapine affects you.

Olanzapine may cause drowsiness in some people.

Be careful when drinking alcohol while taking Apo-Olanzapine.

The effects of alcohol could be made worse while taking olanzapine. Your doctor may suggest you avoid alcohol while you are being treated with Apo-Olanzapine.

Olanzapine may make you feel light headed, dizzy or faint, be careful when getting up from sitting or lying position.

Getting up slowly may help.

If outdoors, wear protective clothing and use at least a 30+ sunscreen.

Olanzapine may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn.

If your skin does appear to be burning, tell your doctor.

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.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Olanzapine.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much olanzapine, it may cause fast heartbeat, agitation/aggression, difficulty speaking, uncontrollable movements and sedation.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Olanzapine or if you have any questions or concerns.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

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

Tell your doctor or if you notice any of the following:

This list includes the most common side effects.

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

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 if you notice any of the above side effects and they worry you.

Tell your doctor immediately if you notice any of the following.

These may be serious side effects. 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 or allergic reaction
- slow heart beat
- 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 or someone you know or care for experience any of the following, stop taking olanzapine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

- Sudden signs of an allergic reaction such as skin rash, itching, shortness of breath or swelling of the face, lips or tongue
- 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
- severe upper stomach pain often with nausea and vomiting (inflammation of the pancreas)
- 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
- pain/tenderness in the calf muscle area
- muscle pain, muscle weakness and brown urine
- heart palpitations and dizziness which may lead to collapse
- fainting or passing out
- fast, slow or irregular heartbeat
- thoughts of suicide or attempting suicide or self-harm.

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

The following additional side effects may occur in some groups of people taking olanzapine:

Elderly patients with dementia-related psychosis

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

- unusual manner of walking
- falls
- pneumonia
- involuntary passing of urine

Parkinson's disease psychosis

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.

Olanzapine in combination with lithium or valproate

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

- tremors
- speech disorder

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.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Apo-Olanzapine

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.

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.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

Product description

What it looks like

Apo-Olanzapine film coated tablets

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

APO-OLANZAPINE 5mg film coated tablet: White, round, biconvex film-coated tablet. Engraved "APO" on one side, "OLA" over "5" on the other side.

APO-OLANZAPINE 7.5mg film coated tablet: White, round, biconvex film-coated tablet. Engraved "APO" on one side, "OLA" over "7.5" on the other side.

APO-OLANZAPINE 10mg film coated tablet: White, round, biconvex film-coated tablet. Engraved "APO" on one side, "OLA" over "10" on the other side.

APO-OLANZAPINE 15mg film coated tablet: Light blue, elliptical, biconvex film-coated tablet. Engraved "APO" on one side, "OLA 15" on the other side.

APO-OLANZAPINE 20mg film coated tablet: Light pink, elliptical, biconvex film-coated tablet. Engraved "APO" on one side, "OLA 20" on the other side.

Film coated tablet cannot be halved.

APO-OLANZAPINE 2.5mg, 5mg, 7.5mg, 10mg, 15mg & 20mg film coated tablets are available as:

- Blister packs of 28 tablets
- Bottles of 100 or 500 tablets.

Apo-Olanzapine ODT orally disintegrating tablets

APO-OLANZAPINE ODT 5mg orally disintegrating tablet: Yellow, round, flat faced radial edge tablet. Engraved "APO" on one side, "OL" over "5" on the other side.

APO-OLANZAPINE ODT 10mg orally disintegrating tablet: Yellow, round, flat faced radial edge tablet. Engraved "APO" on one side, "OL" over "10" on the other side.

APO-OLANZAPINE ODT 15mg orally disintegrating tablet: Yellow, round, flat faced radial edge tablet. Engraved "APO" on one side, "OL" over "15" on the other side.

APO-OLANZAPINE ODT 20mg orally disintegrating tablet: Yellow, round, flat faced radial edge tablet. Engraved "APO" on one side, "OL" over "20" on the other side.

Orally disintegrating tablet cannot be halved.

APO-OLANZAPINE ODT 5mg, 10mg, 15mg & 20mg orally-disintegrating tablets are available as:

- Blister packs of 28 tablets
- Bottles of 100 or 500 tablets.

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

Ingredients

Active ingredient:

Apo-Olanzapine film coated tablets

Each tablet contains 2.5mg, 5mg, 7.5mg, 10mg, 15mg or 20mg of Olanzapine as the active ingredient.

Apo-Olanzapine ODT orally disintegrating tablets

Each tablet contains 5mg, 10mg, 15mg or 20mg of Olanzapine as the active ingredient.

Inactive ingredients:

Apo-Olanzapine film coated tablets contain the following excipients:

- Lactose Monohydrate
- Microcrystalline Cellulose
- Corn Starch
- Magnesium Stearate (Vegetable Source)
- Hydroxypropyl Methylcellulose
- Hydroxypropyl Cellulose Type LF
- Polyethylene Glycol 8000
- Titanium Dioxide

The 15mg strength contains additionally colourant:

- Indigotine Al Lake 12-14% (Blue#2)

The 20mg strength contains additionally colourant:

- Red Ferric Oxide and Yellow Ferric Oxide

This medicine contains lactose.

The 15mg tablet contains a colourant that contains sulphur

This medicine is gluten free.

APO-OLANZAPINE ODT orally disintegrating tablets contain the following excipients:

- Mannitol
- Microcrystalline Cellulose
- Carboxymethylcellulose Calcium
- Sucralose
- Magnesium Stearate (Vegetable Source)
- Colloidal Silicon Dioxide.

This medicine contains sucralose and mannitol.

This medicine is gluten free.

Sponsor Details

Apo-Olanzapine is supplied in New Zealand by:

Apotex NZ Ltd
32 Hillside Road
Glenfield
AUCKLAND 0627

Telephone: (09) 444 2073

Fax: (09) 444 2951

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