

# **APO-Olanzapine Orally Disintegrating Tablets**

## **Orally Disintegrating Tablets**

Olanzapine

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### **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 this medicine. 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 taking 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 need to read it again.

## **What this medicine 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.

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 mood stabiliser that prevents further occurrences of high and low (depressed) extremes of mood associated with 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.

This medicine may affect your ability to drive a car or operate machinery.

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 have an allergy to:**

- any medicine containing olanzapine
- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include:

- 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

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy. Your doctor will discuss with you the risks and benefits involved.

**Do not breastfeed if you are taking this medicine.**

Olanzapine passes into breastmilk and there is a possibility that your baby may be affected.

**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 (a small gland at the base of the brain)

- chest infection e.g. pneumonia
- bone marrow depression
- 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.

**Tell your doctor if you are pregnant or plan to become pregnant or start breastfeeding.**

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

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

**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.

## **Taking other medicines**

**Tell your doctor or pharmacist 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 and olanzapine may interfere with each other. 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 to treat 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.

These medicines may be affected by olanzapine 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.

**Smoking may affect olanzapine or may affect how it works.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## **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.

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

## **How much to take**

Your doctor will tell you how much of this medicine you will need to take each day. 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

## **How to take it**

**Do not handle the orally disintegrating tablet with wet hands.**

It should be handled carefully with dry hands.

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

You can also place the orally disintegrating tablet in a full glass or a cup of water, 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**

#### **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 does not matter if you take it before, with or after food.

### **How long to take it for**

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

Olanzapine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

### **If you forget to take it**

**If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.**

**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 the dose that you missed.**

This may increase the chance of you experiencing unwanted side effects.

**If you are not sure what to do, ask your doctor or pharmacist.**

**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 the 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 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.**

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

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

Olanzapine may affect other medicines used during surgery.

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

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

Olanzapine may interfere with the results of some tests.

**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 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.

## **Things you must not do**

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

If you stop taking it suddenly, your condition may worsen, or your chance of getting an unwanted side effect may increase. To prevent this, your doctor will gradually reduce the amount

of olanzapine you take each day before stopping the medicine completely.

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

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

**Do not take any other medicines that cause drowsiness while you are taking this medicine, unless recommended by 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. If you feel drowsy, do not drive, operate machinery or do anything that could be dangerous.

**Be careful when drinking alcohol while taking olanzapine.**

The effects of alcohol could be made worse while taking olanzapine. Your doctor may suggest you avoid alcohol while being treated with this medicine.

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

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

## **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.**

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

Side effects are likely to vary from patient to patient. Some side effects may be related to the dose of olanzapine. Accordingly, it is important that you tell your doctor as soon as possible about any unwanted effects.

**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

The above list includes the more common side effects of olanzapine.

**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 or allergic reactions

- 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
- stuttering or speech difficulty

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

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

- 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

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

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.

## **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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## **Product description**

### **What APO-Olanzapine ODT looks like**

APO-Olanzapine ODT orally disintegrating tablets are available in the following strengths:

- 5 mg tablet: yellow, round, flat, faced radial-edged tablets. Engraved "APO" on one side, "OL" over "5" on the other side. Blister: AUST R 158995. AUST Bottle: R 158989.
- 10 mg tablet: yellow, round, flat, faced radial-edged tablets. Engraved "APO" on one side, "OL" over "10" on the other side. Blister: AUST R 159001. Bottle: AUST R 158965.
- 15 mg tablet: yellow, round, flat, faced radial-edged tablets. Engraved "APO" on one side, "OL" over "15" on the other side. Blister: AUST R 158992. Bottle: AUST R 158985.
- 20 mg tablet: yellow, round, flat, faced radial-edged tablets. Engraved "APO" on one side, "OL" over "20" on

the other side. Blister: AUST R 158986. Bottle: AUST R 158967.

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 ODT orally disintegrating tablets contains either 5 mg, 10 mg, 15 mg or 20 mg of olanzapine as the active ingredient.

It also contains the following inactive ingredients:

- mannitol
- microcrystalline cellulose
- carmellose calcium
- sucralose
- magnesium stearate
- colloidal anhydrous silica.

This medicine contains sucralose.

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

## **Sponsor**

Apotex Pty Ltd

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