

APO-OLANZAPINE ODT TABLETS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-OLANZAPINE ODT?

APO-OLANZAPINE ODT contains the active ingredient olanzapine. APO-OLANZAPINE ODT is used to help correct chemical imbalances in the brain, which may cause mental illness.

For more information, see Section [1. Why am I using APO-OLANZAPINE ODT?](#) in the full CMI.

2. What should I know before I use APO-OLANZAPINE ODT?

Do not use if you have ever had an allergic reaction to olanzapine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-OLANZAPINE ODT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-OLANZAPINE ODT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-OLANZAPINE ODT?

Your doctor will tell you how many tablets you should take. The dose your doctor will prescribe will usually be in the range of 5 mg to 20 mg per day.

More instructions can be found in Section [4. How do I use APO-OLANZAPINE ODT?](#) in the full CMI.

5. What should I know while using APO-OLANZAPINE ODT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-OLANZAPINE ODT.• Tell your doctor if you become pregnant while taking APO-OLANZAPINE ODT.• Keep all your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine, or change the dosage, without first checking with your doctor.• Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how APO-OLANZAPINE ODT affects you. APO-OLANZAPINE ODT may cause drowsiness in some people.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol. The effects of alcohol could be made worse while taking APO-OLANZAPINE ODT.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in a cool dry place where the temperature stays below 25°C.• Keep this medicine where children cannot reach it.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Like other medicines, APO-OLANZAPINE ODT may cause some unwanted side effects. These are likely to vary from patient to patient. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-OLANZAPINE ODT TABLETS

Active ingredient(s): *olanzapine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-OLANZAPINE ODT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-OLANZAPINE ODT.**

Where to find information in this leaflet:

- [1. Why am I using APO-OLANZAPINE ODT?](#)
- [2. What should I know before I use APO-OLANZAPINE ODT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-OLANZAPINE ODT?](#)
- [5. What should I know while using APO-OLANZAPINE ODT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-OLANZAPINE ODT?

APO-OLANZAPINE ODT contains the active ingredient olanzapine. Olanzapine belongs to a group of medicines called antipsychotics.

APO-OLANZAPINE ODT 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.

2. What should I know before I use APO-OLANZAPINE ODT?

Warnings

Do not use APO-OLANZAPINE ODT if:

- you are allergic to olanzapine, or 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.

- Always check the ingredients to make sure you can use this medicine.
- 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.

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)
- disease of the blood or bone marrow 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 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
- DRESS, a severe drug reaction to olanzapine, with a combination of three or more of the following: rash, eosinophilia (higher number of a group of white blood cells), fever, swollen lymph nodes or inflammation of liver, kidney, lung, or heart
- tardive dyskinesia, a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs.
- Akathisia, a subjective feeling of restlessness and difficulty sitting still
- sleep apnoea, a sleep disorder where a person has pauses in breathing or periods of shallow breathing during sleep.
- if you are elderly with dementia-related psychosis
- if you have previously had a stroke or transient ischaemic attack (mini-stroke) or if you have high blood pressure.

Tell your doctor if:

- you will be in a hot environment or do a lot of vigorous exercise. APO-OLANZAPINE ODT may make you sweat less, causing your body to overheat.
- you smoke. Smoking may affect APO-OLANZAPINE ODT or may affect how it works.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

Like most antipsychotic medicines, APO-OLANZAPINE ODT is not recommended for use during pregnancy.

Newborn babies of mothers taking antipsychotic drugs (including APO-OLANZAPINE ODT) during the last trimester of pregnancy are at risk of experiencing extrapyramidal neurological disturbances and/or withdrawal symptoms following delivery. These may include, but are not limited to agitation, tremor, muscle stiffness or weakness, drowsiness, feeding problems, and breathing difficulty. If there is a need to consider APO-OLANZAPINE ODT during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is recommended that you do not breast-feed while taking APO-OLANZAPINE ODT.

3. What if I am taking other medicines?

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

Some medicines may be affected by APO-OLANZAPINE ODT or affect how it works.

These include:

- medicines used to treat a fast or irregular heartbeat (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 or strong pain killers)
- 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 that can change the heart's electrical activity or make it more likely to change
- activated charcoal

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking APO-OLANZAPINE ODT.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-OLANZAPINE ODT.

4. How do I use APO-OLANZAPINE ODT?

How much to take

- Your doctor will tell you how many APO-OLANZAPINE ODT tablets you should take. The dose your doctor will prescribe for you will usually be in the range 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.
- Follow the instructions provided and use APO-OLANZAPINE ODT until your doctor tells you to stop.

When to take APO-OLANZAPINE ODT

- APO-OLANZAPINE ODT should be taken once a day as advised by your doctor.
- Take your prescribed dose at the same time each day.
- APO-OLANZAPINE ODT can be taken before, with or after food.

How to take APO-OLANZAPINE ODT

- 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.

How long to take APO-OLANZAPINE ODT

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 use APO-OLANZAPINE ODT

APO-OLANZAPINE ODT should be used regularly at the same time each day. If you forget take it, take it as soon as you remember then go back to taking your medicine as you would normally.

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

Do not take a double dose to make up for the dose you missed. This may increase the chance of you experiencing side effects.

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

If you use too much APO-OLANZAPINE ODT

If you think that you have used too much APO-OLANZAPINE ODT, you may need urgent medical attention. If you have taken too much APO-OLANZAPINE ODT, the most common signs are fast heartbeat, agitation/aggression, difficulty speaking, uncontrollable movements and sleepiness (sedation).

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using APO-OLANZAPINE ODT?

Things you should do

- It is important that you remember to take APO-OLANZAPINE ODT daily and at the dose prescribed by your doctor.
- Tell all doctors, dentists and pharmacists who are treating you that you are taking APO-OLANZAPINE ODT.
- While you are taking APO-OLANZAPINE ODT, tell your doctor or pharmacist before you start any new medicine.

If you become pregnant or start breastfeeding while taking APO-OLANZAPINE ODT, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

- Your doctor should monitor your weight while you are taking APO-OLANZAPINE ODT.
- Patients with diabetes or who have a higher chance of developing diabetes should have their blood sugar checked often.
- Your doctor may request you have a blood test from time to time to monitor your cholesterol levels.
- 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.

All thoughts of suicide or violence must be taken seriously.

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.

Things you should not do

- Do not stop using APO-OLANZAPINE ODT or lower the dosage, even if you feel better, without checking with your doctor.
- Do not give APO-OLANZAPINE ODT to anyone else, even if their symptoms seem similar or they have the same condition as you. Your doctor has prescribed this medication for you and your condition.

Things to be careful of

- Smoking may affect APO-OLANZAPINE ODT or may affect how it works.
- If APO-OLANZAPINE ODT makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help.
- If outdoors, wear protective clothing and use at least a 30+ sunscreen. APO-OLANZAPINE ODT 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. APO-OLANZAPINE ODT may affect the way your body reacts to temperature changes.
- Antipsychotics have the potential to cause cardiac complications and sudden cardiac death

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-OLANZAPINE ODT affects you.

APO-OLANZAPINE ODT may cause drowsiness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while taking APO-OLANZAPINE ODT.

The effects of alcohol could be made worse while taking APO-OLANZAPINE ODT.

Your doctor may suggest you avoid alcohol while you are being treated with APO-OLANZAPINE ODT.

Looking after your medicine

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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or

- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Like other medicines, APO-OLANZAPINE ODT may cause some unwanted side effects. These are likely to vary from patient to patient. Some side effects may be related to the dose of APO-OLANZAPINE ODT. Accordingly, it is important that you tell your doctor as soon as possible about any unwanted effects. Your doctor may then decide to adjust the dose of APO-OLANZAPINE ODT you are taking.

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 APO-OLANZAPINE ODT for a few days.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • drowsiness • unusual tiredness or weakness • fever • restlessness or difficulty sitting still • increased appetite, weight gain • constipation or bloating • dry mouth • swelling of your hands, feet and ankles • aching joints • nose bleeds • dizziness, confusion, forgetfulness • speech disorder • sleepwalking • sleep eating 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) which occur more quickly than normal • rash or allergic reaction • slow heartbeat • changes in sexual functioning or sex drive in men or women 	<p>Tell your doctor as soon as possible if you notice any of these side effects.</p> <p>These side</p>

<ul style="list-style-type: none"> • 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 • lipid alterations, such as high blood fat values (cholesterol and triglycerides) • reaction following abrupt discontinuation (profuse sweating, nausea or vomiting) • absence of menstrual periods, changes in the regularity of menstrual periods • involuntary passing of urine or difficulty in initiating urination • unusual hair loss or thinning 	<p>effects are uncommon but may require medical attention.</p>
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Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> • Sudden signs of an allergic reaction such as a 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 • painful swollen leg, chest pain, or shortness of breath as these can be signs of blood clots in the lungs or legs • seizures, fits or convulsions • 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 • sudden decrease in body temperature, intense trembling, lethargy, confusion, slow heartbeat and slow breathing 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> • 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 attack • heart palpitations and dizziness, which may lead to collapse • fast breathing, shortness of breath, fever with chills, feeling tired or weak, chest pain while coughing, fast heartbeat. You may have pneumonia. • fever or swollen glands, especially if they occur together with or shortly after a skin rash 	
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The following additional side effects may occur in some groups of people taking APO-OLANZAPINE ODT:

Elderly patients with dementia-related psychosis

- unusual manner of walking
- falls
- pneumonia
- involuntary passing of urine.
- stroke
- transient ischemic attack – symptoms maybe, but not limited to, paralysis in face, arm or leg.

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.

In combination with lithium or valproate

Patients with bipolar mania taking APO-OLANZAPINE ODT in combination with lithium or valproate may notice the following additional side effects:

- tremors
- speech disorder
- dry mouth
- weight gain.

Do not be alarmed by this list of side effects. Most of these side effects are very rare. You may not experience any of them.

Your doctor has weighed the risks of using this medicine against the benefits they expect you to have.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-OLANZAPINE ODT contains

Active ingredient (main ingredient)	olanzapine
Other ingredients (inactive ingredients)	mannitol microcrystalline cellulose carmellose calcium sucralose magnesium stearate colloidal anhydrous silica
Potential allergens	Contains sucralose.

Do not take this medicine if you are allergic to any of these ingredients.

What APO-OLANZAPINE ODT looks like

APO-OLANZAPINE ODT 5 mg tablets are yellow, round, flat faced radial edged tablets engraved with 'APO' on one side, "OL" over "5" on the other side. (Blister Aust R 158995. Bottle: AUST R 158989).

APO-OLANZAPINE ODT 10 mg tablets are yellow, round, flat faced radial edged tablets engraved with 'APO' on one side, "OL" over "10" on the other side. (Blister: AUST R 159001. Bottle: AUST R 158965).

APO-OLANZAPINE ODT 15 mg tablets are yellow, round, flat faced radial edged tablets engraved with 'APO' on one

side, “OL” over “15” on the other side. (Blister: AUST R 158992. Bottle: AUST R 158985).

APO-OLANZAPINE ODT 20 tablets are yellow, round, flat faced radial edged tablets engraved with ‘APO’ on one side, “OL” over “15” on the other side. (Blister: AUST R 158986. Bottle: AUST R 158967).

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.

Who distributes APO-OLANZAPINE ODT

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

CREMORNE VIC 3121

www.arrotex.com.au

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