

Olanzapine Sandoz®

olanzapine film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Olanzapine Sandoz.

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 Olanzapine Sandoz is used for

This medicine 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 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.

It contains the active ingredient olanzapine.

Olanzapine belongs to a group of medicines called antipsychotics.

It works by helping 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 it for another reason.

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

Olanzapine is not recommended for use in children under the age of 18 years as there is not enough information on its effects in this age group.

Before you take Olanzapine Sandoz

When you must not take it

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

- olanzapine, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the 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 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)
- 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
- tardive dyskinesia, a reaction to some medicines with uncontrollable twitching or jerking movement of the arms and legs
- sleep apnoea, a sleep disorder where a person has pauses in breathing or periods of shallow breathing during sleep. Not limited to agitation, tremor, muscle stiffness or weakness, drowsiness, feeding problems, and breathing difficulty

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

Like most antipsychotic medicines, Olanzapine Sandoz is not recommended for use during pregnancy. Newborn babies of mothers taking antipsychotic drugs (including olanzapine) 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 this medicine during your pregnancy your doctor will discuss with you the risks and benefits of using it.

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is recommended that you do not breast-feed while taking this medicine.

Tell your doctor if you suffer from lactose intolerance (because Olanzapine Sandoz tablets contain lactose).

Tell your doctor if you will be in a hot environment or do a lot of vigorous exercise.

Olanzapine Sandoz may make you sweat less, causing your body to overheat.

Tell your doctor if you smoke.

Smoking may affect Olanzapine Sandoz or may affect how it works.

If you are elderly with dementia-related psychosis, tell your doctor if you have previously had a stroke or transient ischaemic attack (mini-stroke) or if you have high blood pressure. **This medicine is not recommended for use in children under the age of 18 years.**

If you have not told your doctor about any of the above, tell him/her before you start taking Olanzapine Sandoz.

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 Sandoz 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
- medicines taken for depression
- carbamazepine, a medicine used for mood stabilisation and to treat epilepsy
- other centrally acting medicines (e.g. tranquillisers or strong painkillers)
- ciprofloxacin, a medicine used to treat bacterial infections
- medicines that lower blood pressure
- 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 Olanzapine Sandoz or may affect

how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take Olanzapine Sandoz

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

They may differ from the information contained in this leaflet.

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

How much to take

Your doctor will tell you how many 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.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Olanzapine Sandoz may not work as well and your condition may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

When to take Olanzapine Sandoz

Olanzapine Sandoz tablets should be taken once a day as advised by your doctor.

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.

Olanzapine Sandoz can be taken with or without food.

How long to take Olanzapine Sandoz

Continue taking your medicine for as long as your doctor tells you. Do not stop taking Olanzapine Sandoz just because you feel better. It is important that you do NOT stop taking Olanzapine Sandoz unless your doctor tells you.

This medicine 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

Take your dose as soon as you remember, and continue to take it 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 that you missed.

This may increase the chance of you getting an unwanted side effect.

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 Australia 13 11 26 or New Zealand 0800 POISON

or 0800 764766) 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 Olanzapine Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include a fast heartbeat, agitation/aggression, difficulty speaking, uncontrollable movements and sleepiness (sedation).

While you are taking Olanzapine Sandoz

Things you must do

It is important that you remember to take Olanzapine Sandoz daily and at the 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 Olanzapine Sandoz.

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

If you become pregnant while taking this medicine, 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 this medicine.
- 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 must not do

Do not take Olanzapine Sandoz to treat any other complaints unless your doctor tells you to.

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

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

Your doctor may want you to gradually reduce the amount you are taking before stopping completely.

Things to be careful of

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

This medicine may cause drowsiness in some people. If you experience this symptom, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

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

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood

pressure. If this problem continues or gets worse, talk to your doctor.

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

Olanzapine Sandoz 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.

This medicine may affect the way your body reacts to temperature changes.

Antipsychotics have the potential to cause cardiac complications and sudden cardiac death.

Side effects

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

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.

Side effects are likely to vary from patient to patient. Some side effects may be related to the dose of your medicine. 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 the medicine you are taking.

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 or pharmacist if you notice any of the following and they worry you:

- drowsiness

- unusual tiredness or weakness
- fever
- restlessness or difficulty sitting still
- increased appetite, weight gain
- constipation, bloating
- dry mouth
- swelling of your hands, feet and ankles
- aching joints
- nose bleeds
- dizziness, confusion, forgetfulness
- speech disorder
- 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 Sandoz for a few days.

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

These are the more common side effects of Olanzapine Sandoz.

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 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
- involuntary passing of urine or difficulty in initiating urination
- unusual hair loss or thinning.

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

These side effects are uncommon but may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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

- 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. Most of these side effects are very rare.

The following additional side effects may occur in some group of people taken olanzapine.

Elderly patients with dementia-related psychosis

may notice the following side effects:

- unusual manner of walking
- falls
- pneumonia
- inability to retain urine
- stroke
- transient ischaemic attack - symptoms may be, 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.

Olanzapine Sandoz in combination with lithium or valproate

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

- tremors

- speech disorder.

These are the more common side effects of Olanzapine Sandoz.

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 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 of these 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.

After taking Olanzapine Sandoz

Storage

Keep your medicine in the original container until it is time to take them.

If you take it out of its original container it may not keep well.

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

Do not store Olanzapine Sandoz 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 it 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 it looks like

Olanzapine Sandoz comes in four types of tablets:

Olanzapine Sandoz 2.5 mg - white, round, film-coated tablet.

Olanzapine Sandoz 5 mg - white, round, film-coated tablet with breaking notch on one side.

Olanzapine Sandoz 7.5 mg - white, round, film-coated tablet.

Olanzapine Sandoz 10 mg - white, round, film-coated tablet with breaking notch on one side.

Available in blisters of 28 tablets.

Ingredients

Active ingredients:

- Olanzapine Sandoz 2.5 mg - 2.5 mg olanzapine
- Olanzapine Sandoz 5 mg - 5 mg olanzapine
- Olanzapine Sandoz 7.5 mg - 7.5 mg olanzapine
- Olanzapine Sandoz 10 mg - 10 mg olanzapine

Inactive ingredients:

- lactose monohydrate
- hypromellose
- microcrystalline cellulose
- croscopolone
- magnesium stearate
- OPADRY II 85F18422 white - containing polyvinyl alcohol, polyethylene glycol, titanium dioxide (E 171), indigo carmine (15mg tablets only), iron oxide red (20mg tablets only) and talc.

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

Supplier

Olanzapine Sandoz is supplied in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Australian Register Number(s)

2.5 mg tablets: AUST R 148450
(blisters)

5 mg tablets: AUST R 148469
(blisters)

7.5 mg tablets: AUST R 148474
(blisters)

10 mg tablets: AUST R 148451
(blisters)

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