

OLANZAPINE SANDOZ® ODT

olanzapine orally dispersible tablets

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine. It does not contain all the available information and does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

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

What OLANZAPINE SANDOZ ODT is used for

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

OLANZAPINE SANDOZ ODT is used to treat symptoms of schizophrenia and related psychoses. OLANZAPINE SANDOZ ODT alone, or in combination with lithium or valproate, is used for the short-term treatment of acute manic episodes associated with Bipolar I Disorder.

OLANZAPINE SANDOZ ODT is also a mood stabiliser that prevents further occurrences of the disabling 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.

Your doctor may have prescribed OLANZAPINE SANDOZ ODT for another reason.

Ask your doctor if you have any questions about why OLANZAPINE SANDOZ ODT has been prescribed for you.

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

OLANZAPINE SANDOZ ODT 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 taking OLANZAPINE SANDOZ ODT

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not take it

Do not take OLANZAPINE SANDOZ ODT:

- if you have had an allergic reaction to olanzapine or to any of the ingredients

listed at the end of this leaflet (see 'Product Description').

Signs of an allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.

- if the packaging is torn or shows signs of tampering or the tablets do not look quite right.
- if the expiry date on the pack has passed.
If you take this medicine after the expiry date has passed it may not work as well.

If you are not sure whether you should start taking OLANZAPINE SANDOZ ODT, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have had an allergic reaction to any medicine which you have taken previously to treat your current condition.

Tell your doctor if 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)
- 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 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
- sleep apnoea, a sleep disorder where a person has pauses in breathing or periods of shallow breathing during sleep

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

Like most antipsychotic medicines, OLANZAPINE SANDOZ ODT is not recommended for use during pregnancy. If there is a need to consider OLANZAPINE SANDOZ ODT during your pregnancy, your doctor will discuss with you the benefits and risks of using it. Shaking, muscle stiffness and difficulty in feeding, all of which are reversible, may occur in newborns, if a mother uses the medicine in the last trimester of her pregnancy. OLANZAPINE SANDOZ ODT should be used in pregnancy only if the anticipated benefit outweighs the risk and the

administered dose and duration of treatment should be as low and as short as possible.

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

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

Tell your doctor if you suffer from lactose intolerance (because OLANZAPINE SANDOZ ODT contains lactose).

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

OLANZAPINE SANDOZ ODT may make you sweat less, causing your body to overheat.

OLANZAPINE SANDOZ ODT is not recommended for use in children.

Tell your doctor if you smoke.

Smoking may affect OLANZAPINE SANDOZ ODT 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

Taking other medicines

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

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

Smoking may affect OLANZAPINE SANDOZ ODT or may affect how it works.

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

Tell your doctor about these things before you take OLANZAPINE SANDOZ ODT.

How to take OLANZAPINE SANDOZ ODT

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

These may differ from the information contained in this leaflet.

How much to take

OLANZAPINE SANDOZ ODT orally dispersible tablets:

Your doctor will tell you how many OLANZAPINE SANDOZ 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.

How to take it

OLANZAPINE SANDOZ ODT:

These orally disintegrating tablets will dissolve in your mouth, therefore do not require water.

You can also place these tablets in a full glass 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 tablets should not be placed in cola drinks.

When to take it

OLANZAPINE SANDOZ ODT should be taken once a day as advised by your doctor.

Take your prescribed dose at the same time each day.

OLANZAPINE SANDOZ ODT can be taken with or without food.

How long to take it

Do not stop taking OLANZAPINE SANDOZ ODT just because you feel better. It is important that you do NOT stop taking OLANZAPINE SANDOZ ODT unless your doctor tells you.

If you forget to take it

If it is almost time for 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 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.

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

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much OLANZAPINE SANDOZ ODT. Do this even if there are no signs of discomfort or poisoning.

If you have taken too much OLANZAPINE SANDOZ ODT, the most common signs are fast heart beat, agitation/aggression, difficulty speaking, uncontrollable movements and sleepiness (sedation).

While you are taking OLANZAPINE SANDOZ ODT

Things you must do

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

Tell all doctors, dentists and pharmacists who are treating you that you are taking OLANZAPINE SANDOZ ODT.

While you are taking OLANZAPINE SANDOZ ODT, tell your doctor or pharmacist before you start any new medicine.

If you become pregnant while taking OLANZAPINE SANDOZ ODT, tell your doctor.

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

- Your doctor should monitor your weight while you are taking OLANZAPINE SANDOZ 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 must not do

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

Do not give OLANZAPINE SANDOZ ODT to anyone else, even if their symptoms seem similar or they have the same condition as you.

Your doctor has prescribed OLANZAPINE SANDOZ ODT for you and your condition.

Things to be careful of

OLANZAPINE SANDOZ ODT may cause drowsiness in some people.

Be careful driving or operating machinery until you know how OLANZAPINE SANDOZ ODT affects you.

Be careful when drinking alcohol while taking OLANZAPINE SANDOZ ODT. The effects of alcohol could be made worse while taking OLANZAPINE SANDOZ ODT.

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

If OLANZAPINE SANDOZ ODT makes you feel lightheaded, 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.

OLANZAPINE SANDOZ 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.

OLANZAPINE SANDOZ ODT 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 experience any undesirable effect or feel unwell while you are taking OLANZAPINE SANDOZ ODT.

Like other medicines, OLANZAPINE SANDOZ 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 OLANZAPINE SANDOZ 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 OLANZAPINE SANDOZ ODT you are taking.

Tell your doctor if you notice any of the following side effects and they worry you:

- drowsiness
- unusual tiredness or weakness
- fever
- restlessness or difficulty sitting still
- dizziness, confusions, forgetfulness
- increased appetite, weight gain
- constipation, bloating
- dry mouth
- swelling of your hands, feet and ankles
- nose bleeds
- aching joints
- 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 ODT 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 ODT.

Tell your doctor if you notice any of the following side effects:

- 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.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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
- 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 heart beat, 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

These are 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 taking olanzapine.

Elderly patients with dementia-related psychosis

may notice the following side effects:

- unusual manner of walking
- falls
- pneumonia

- involuntary passing of 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 ODT in combination with lithium or valproate

Patients with bipolar mania taking OLANZAPINE SANDOZ ODT 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 ODT.

Also, 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.

Do not be alarmed by this list of side effects.

You may not experience any of them.

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

Tell your doctor if you notice anything else that is making you feel unwell.

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.

After taking OLANZAPINE SANDOZ ODT

Storage

Keep your tablets in the blister pack until it is time to take them.

Keep your tablets in a cool, dry place where the temperature stays below 30°C.

All medicines should be kept where young children cannot reach them.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Do not take OLANZAPINE SANDOZ ODT after the expiry date on the pack has passed.

Disposal

If your doctor tells you to stop taking OLANZAPINE SANDOZ ODT or you find that the tablets have passed their expiry date, please return any left over tablets or wafers to your pharmacist.

Product Description

What it looks like

OLANZAPINE SANDOZ ODT orally disintegrating tablets:

- 5 mg: Yellow, round, biconvex orally disintegrating tablets - blister packs of 7 and 28
- 10 mg: Yellow, round, flat orally disintegrating tablets - blister packs of 7 and 28

- 15 mg: Yellow, round, biconvex orally disintegrating tablets - blister packs of 7 and 28
- 20 mg: Yellow, round, flat orally disintegrating tablets - blister packs of 7 and 28

Not all strengths and pack sizes may be available.

Ingredients

Active ingredient

OLANZAPINE SANDOZ ODT contains the active ingredient, Olanzapine:

- 5 mg - 5 mg Olanzapine per tablet
- 10 mg - 10 mg Olanzapine per tablet
- 15 mg - 15 mg Olanzapine per tablet
- 20 mg - 20 mg Olanzapine per tablet

OLANZAPINE SANDOZ ODT orally disintegrating tablets:

- lactose monohydrate
- crospovidone
- hypromellose
- colloidal anhydrous silica
- purified talc
- magnesium stearate
- mint Flavouring E-0613218 (acacia, cineole, maltodextrin, mint oil, mint oil dementholised, peppermint oil, menthone, isomenthone, menthyl acetate and menthol)

Supplier

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

Australian Registration Numbers

OLANZAPINE SANDOZ ODT (orally disintegrating tablets)

5 mg AUST R 179092
10 mg AUST R 179086
15 mg AUST R 179073
20 mg AUST R 179093

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