

OLANZAPINE-DRLA, OLANZAPINE ODT-DRLA

Olanzapine

Consumer Medicine Information

Except where indicated, "Olanzapine-DRLA" refers to both the Olanzapine-DRLA tablets and the Olanzapine ODT-DRLA orally disintegrating tablet.

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 with your doctor.

The information in this leaflet was last updated on the date shown on the final page. More recent information about this medicine may be available. Make sure you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. The updated leaflet may contain important information about Olanzapine-DRLA and its use that you should be aware of.

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-DRLA is used for

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

Olanzapine-DRLA is used to treat symptoms of schizophrenia and related psychoses. Schizophrenia is a mental illness with disturbances in thinking, feelings and behaviour.

Olanzapine-DRLA 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-DRLA is also 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 Olanzapine-DRLA for another reason.

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

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

Olanzapine-DRLA 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-DRLA

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-DRLA:

- **if you have had an allergic reaction to any type of Olanzapine-DRLA 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 or orally disintegrating 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-DRLA, 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.

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

Like most antipsychotic medicines, Olanzapine-DRLA is not recommended for use during pregnancy. If there is a need to consider Olanzapine-DRLA during your pregnancy, your doctor will discuss with you the benefits and risks 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 Olanzapine-DRLA.

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

Tell your doctor if you suffer from phenylketonuria (because OLANZAPINE ODT-DRLA orally disintegrating tablets contain aspartame). Tell your doctor if you will be in a hot environment or do a lot of vigorous exercise.

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

Tell your doctor if you smoke
Smoking may affect Olanzapine-DRLA or may affect how it works

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-DRLA 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 depression
- carbamazepine, a medicine used for mood stabilisation and to treat epilepsy
- other centrally acting medicines (eg. tranquillisers)
- 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.

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

Tell your doctor about these things before you take Olanzapine-DRLA.

How to take Olanzapine-DRLA

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-DRLA tablets or orally disintegrating tablets:

Your doctor will tell you how many Olanzapine-DRLA tablets or orally disintegrating 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-DRLA tablets:

Olanzapine-DRLA tablets should be swallowed whole with a glass of water.

OLANZAPINE ODT-DRLA orally disintegrating tablets:

OLANZAPINE ODT-DRLA orally disintegrating tablets break easily, so you should handle them carefully.

Do not handle the orally disintegrating tablets with wet hands as the tablets may break up.

1. **Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.**
2. **Carefully peel off the backing.**
3. **Gently push the orally disintegrating tablet out.**

4. **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 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

Olanzapine-DRLA tablets or orally disintegrating tablets should be taken once a day as advised by your doctor.

Take your prescribed dose at the same time each day.

Olanzapine-DRLA tablets or orally disintegrating tablets can be taken with or without food.

How long do I take it

Do not stop taking Olanzapine-DRLA just because you feel better. It is important that you do NOT stop taking Olanzapine-DRLA 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

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-DRLA. Do this even if there are no signs of discomfort or poisoning.

If you have taken too much Olanzapine-DRLA, the most common signs are fast heartbeat, agitation/aggression, difficulty speaking, uncontrollable movements and sedation.

While you are taking Olanzapine-DRLA

Things you must do

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

Tell all doctors, dentists and pharmacists who are treating you that you are taking Olanzapine-DRLA.

While you are taking Olanzapine-DRLA, tell your doctor or pharmacist before you start any new medicine.

If you become pregnant while taking Olanzapine-DRLA, 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-DRLA.
- 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.

Things you must not do

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

Do not give Olanzapine-DRLA to anyone else, even if their symptoms seem similar or they have the same condition as you.

Your doctor has prescribed Olanzapine-DRLA for you and your condition.

Things to be careful of

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

Olanzapine-DRLA may cause drowsiness in some people.

Be careful when drinking alcohol while taking Olanzapine-DRLA.

The effects of alcohol could be made worse while taking Olanzapine-DRLA.

Your doctor may suggest you avoid alcohol while you are being treated with Olanzapine-DRLA.

If Olanzapine-DRLA 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.

Olanzapine-DRLA 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-DRLA may affect the way your body reacts to temperature changes

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you

Like other medicines, Olanzapine-DRLA 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-DRLA. 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-DRLA 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
- increased appetite, weight gain
- constipation, bloating
- dry mouth
- swelling of your hands, feet and ankles
- aching joints
- 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-DRLA 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-DRLA.

Tell your doctor as soon as possible 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

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 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
- 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 palpitations and dizziness which may lead to collapse.

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

All of these side effects are very rare.

The following additional side effects may occur in some groups of people taking Olanzapine-DRLA:

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-DRLA in combination with lithium or valproate

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

- tremors
- speech disorder.

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.

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.

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.

After taking Olanzapine-DRLA

Storage

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

Keep your tablets and orally disintegrating tablets in a cool, dry place, out of direct light and where the temperature stays below 25°C.

Do not store Olanzapine-DRLA or any other medicine in the bathroom or near a sink

Do not leave your tablets in the car on hot days or on windowsills.

Heat and dampness can destroy some medicines.

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.

There will be an expiry date (month, year) on your Olanzapine-DRLA container.

The medicine should not be taken after this date because it may have lost some of its strength.

Disposal

If your doctor tells you to stop taking Olanzapine-DRLA or you find that the tablets or orally disintegrating tablets have passed their expiry date, please return any leftover tablets or

orally disintegrating tablets to your pharmacist.

Product Description

What it looks like

Olanzapine-DRLA tablets:

2.5 mg tablet: White to off white, film coated, oval, biconvex tablets, debossed "OLZ" on one side and "2.5" on other side

5 mg tablet: White to off-white, film coated, oval, biconvex tablets, debossed "OLZ" on one side and "5" on other side

7.5 mg tablet: White to off-white, film coated, oval, biconvex tablets, debossed "OLZ" on one side and "7.5" on other side

10 mg tablet: White to off-white, film coated, oval, biconvex tablets, debossed "OLZ" on one side and "10" on other side.

OLANZAPINE ODT-DRLA orally disintegrating tablets:

5 mg tablet: Yellow coloured, round shaped tablets, convex on one side and flat on the other

10 mg tablet: Yellow coloured, round shaped tablets, convex on one side and flat on the other side

Ingredients

Olanzapine-DRLA tablets: Active Ingredient:

2.5 mg tablet - 2.5 mg olanzapine per tablet

5 mg tablet - 5 mg olanzapine per tablet

7.5 mg tablet - 7.5 mg olanzapine per tablet

10 mg tablet - 10 mg olanzapine per tablet.

Inactive Ingredients - lactose, cellulose - microcrystalline, crospovidone, hydroxypropylcellulos, magnesium stearate, Opadry complete film coating system OY-58900 WHITE (2.5 mg tablets) PI no.3446, Opadry

complete film coating system 06B580002 WHITE (5 mg, 7.5 mg and 10 mg tablets) PI no. 107258

Olanzapine ODT-DRLA orally disintegrating tablets: Active Ingredient:

5 mg orally disintegrating tablet - 5 mg olanzapine per orally disintegrating tablet

10 mg orally disintegrating tablet - 10 mg olanzapine per orally disintegrating tablet

Inactive ingredients – cellulose-microcrystalline, mannitol, starch - pregelatinised maize, crospovidone, sodium lauryl sulfate, aspartame, guar gum, silica - colloidal anhydrous, magnesium stearate.

Supplier

Dr Reddy's Laboratories (Australia) Pty Ltd
Level 9, 492 St Kilda Road
Melbourne VIC 3004
Australia

Australian Registration Numbers

Olanzapine-DRLA tablets:

2.5 mg tablet - AUST R 163387

5 mg tablet - AUST R 163388

7.5 mg tablet - AUST R 163389

10 mg tablet - AUST R163390

OLANZAPINE ODT-DRLA orally disintegrating tablets:

5 mg orally disintegrating tablet - AUST R 163411

10 mg orally disintegrating tablet - AUST R 163412

This leaflet was revised in October 2016.