

# OLANZAPINE RBX Tablets

Olanzapine

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about OLANZAPINE RBX.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking OLANZAPINE RBX against the benefits it is expected to 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 RBX is used for

OLANZAPINE RBX contains olanzapine as the active ingredient. Olanzapine belong to a group of medicines called antipsychotics. OLANZAPINE RBX helps to correct chemical imbalances in the brain which may cause mental illness.

OLANZAPINE RBX is used to treat symptoms of schizophrenia and related psychoses. Schizophrenia is a mental illness with disturbances in thinking, feeling and behavior.

OLANZAPINE RBX alone, or in combination with lithium or valproate, is also used for the short-term treatment of acute manic episodes associated with bipolar I disorder, an illness where the patient experiences episodes of overactivity, elation or irritability.

OLANZAPINE RBX 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 RBX for another reason.

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

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

### Before you use OLANZAPINE RBX

*When you must not take it*

**Do not take OLANZAPINE RBX:**

- **if you have had allergy to olanzapine or any of the inactive ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction may include skin rash, itching, shortness of

breath, or swelling of the tongue, lips or face.

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

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

*Before you start to take it*

**You must tell your doctor if you:**

- **have allergies to any medicines, foods, preservatives or dyes**
- **if you have had an allergic reaction to any medicine which you have taken previously to treat your current condition**
- **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.
- **if you are pregnant or intend to become pregnant.** Like most antipsychotic medicines, OLANZAPINE RBX is not recommended for use during pregnancy. However, if you need to be given OLANZAPINE RBX during your pregnancy, your doctor will discuss with you the benefits and risk of taking it.
- **if you are breast-feeding or plan to breast-feed.** It is recommended that you do not breast-feed while taking OLANZAPINE RBX, as it may pass into breast milk. There is a possibility that the breast-fed baby may be affected.
- **if you suffer from lactose intolerance** (as OLANZAPINE RBX contains lactose).

OLANZAPINE RBX is not recommended for use in children/adolescents under the age of 18 years.

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

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

**Tell your doctor if you smoke.**

Smoking may affect OLANZAPINE RBX 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 (ministroke) or if you have high blood pressure.**

*Taking other medicines*

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

Some medicines and OLANZAPINE RBX 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 (eg. 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 may affect the heart's electrical activities 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 RBX.

**Tell your doctor about these things before you take OLANZAPINE RBX.**

### How to take OLANZAPINE RBX

**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*

Your doctor or pharmacist will tell you how much OLANZAPINE RBX you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

The usual dose prescribed by your doctor is 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 long to take it*

Continue taking OLANZAPINE RBX for as long as your doctor tells you to. Do not stop taking it unless your doctor tells you to, even if you feel better.

*How to take it*

Swallow OLANZAPINE RBX whole with a glass of water.

### *When to take it*

**OLANZAPINE RBX should be taken once a day as advised by your doctor.**

Take your prescribed dose at the same time each day. OLANZAPINE RBX can be taken with or without food.

### *If you forget to take it*

- **Take it as soon as you remember, and then go back to taking 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 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 (Tel. 131126) for advice, or go to Accident & Emergency at your nearest hospital.**

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

You may need urgent medical attention.

Keep these numbers handy in case of an emergency.

If you take too much OLANZAPINE RBX, the most common signs are fast heart beat, aggression, agitation, difficulty speaking, uncontrollable movements, sleepiness (sedation).

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### **While you are using OLANZAPINE RBX**

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#### *Things you must do*

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

**Tell all doctors, dentists and pharmacists who are treating you that you are taking OLANZAPINE RBX.**

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

**If you become pregnant while taking OLANZAPINE RBX, tell your doctor.**

**Be sure to 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 RBX.

Your doctor will check your progress and may want to take some blood/eye/skin tests from time to time. This helps to prevent unwanted side effects.

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 check 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 give OLANZAPINE RBX to anyone else, even if their symptoms seem similar or they have the same condition as you.**

**Do not take OLANZAPINE RBX to treat any other complaints unless your doctor tells you to.**

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

If you stop taking OLANZAPINE RBX suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of OLANZAPINE RBX you take each day before stopping completely.

Do not take any medicine that causes drowsiness while you are taking OLANZAPINE RBX, unless recommended by your doctor.

### *Things to be careful of*

OLANZAPINE RBX may cause drowsiness in some people. **Be careful driving or operating machinery until you know how OLANZAPINE RBX affects you.**

**Be careful when drinking alcohol while taking OLANZAPINE RBX.**

Combining OLANZAPINE RBX and alcohol can make you sleepier or dizzy. Your doctor may suggest you avoid alcohol while you are being treated with OLANZAPINE RBX.

**If OLANZAPINE RBX 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 SPF 30+ sunscreen.**

OLANZAPINE RBX 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 RBX may affect the way your body reacts to temperature changes. Antipsychotics have the potential to cause cardiac complications and sudden cardiac death.

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### **Side Effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking OLANZAPINE RBX.**

Like other medicines, OLANZAPINE RBX 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 RBX. 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 RBX you are taking.

**Tell your doctor or pharmacist if you notice any of the following side effects and they worry you.**

These are the more common side effects of olanzapine:

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

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 RBX 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 RBX.

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 or pharmacist immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following.**

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

- severe upper stomach pain, often with nausea and vomiting (inflammation of the pancreas)
- sharp chest pain, coughing up of blood, or sudden shortness of breath

- yellowing of the skin and/or eyes
- nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and/or eyes
- pain/tenderness in the calf muscle area
- frequent infection 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
- muscle pain, muscle weakness and brown urine
- 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 signs of allergy such as skin rash, itching, swelling of the face, lips, tongue, shortness of breath
- sudden increase in body temperature, with sweating, fast heart beat, muscle stiffness, high blood pressure and convulsions
- 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

#### **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
- 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.

#### **OLANZAPINE RBX in combination with lithium or valproate**

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

- tremor
- 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. Increase in prolactin level can also 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 possible side effects.**

You may not experience any of them.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

#### **Tell your doctor if you notice anything unusual or if you are in any way concerned about your health.**

Do this even if the problems don't seem to be related to OLANZAPINE RBX, and are not mentioned in this leaflet.

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#### **After using it**

##### *Storage*

**Keep OLANZAPINE RBX in the original pack until it is time to take them.**

**Keep OLANZAPINE RBX in a cool, dry place where the temperature is below 25 degrees C.**

**Do not store OLANZAPINE RBX or any medicine in the bathroom or near a sink. Do not leave medicines in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep OLANZAPINE RBX tablets where children cannot reach it.**

A locked cupboard at least one and a half metres (1.5 m) above the ground is a good place to store medicines.

**Do not leave it in the car or hot days or on window sills.**

##### *Disposal*

**If your doctor tells you to stop taking OLANZAPINE RBX, or your medicine has passed its expiry date, ask your pharmacist what to do with any tablets which may be left over.**

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#### **Product description**

##### *What OLANZAPINE RBX looks like*

OLANZAPINE RBX 2.5 mg are light yellow to yellow, round, biconvex tablets, debossed with 'O4' on one side and plain on the other side.

OLANZAPINE RBX 5 mg are light yellow to yellow, round, biconvex tablets, debossed with 'O5' on one side and plain on the other side.

OLANZAPINE RBX 7.5 mg are light yellow to yellow, round, biconvex tablets, debossed with 'O6' on one side and plain on the other side.

OLANZAPINE RBX 10 mg are light yellow to yellow, round, biconvex tablets, debossed with 'O7' on one side and plain on the other side.

All strengths are available in blister packs containing 28 tablets.

##### *Ingredients*

#### **Active ingredient:**

OLANZAPINE RBX 2.5 mg tablets - 2.5 mg of olanzapine

OLANZAPINE RBX 5 mg tablets - 5 mg of olanzapine

OLANZAPINE RBX 7.5 mg tablets - 7.5 mg of olanzapine

OLANZAPINE RBX 10 mg tablets - 10 mg of olanzapine

#### **Inactive ingredients:**

Microcrystalline cellulose, lactose, hypromellose and magnesium stearate.

OLANZAPINE RBX contains sugars as lactose.

OLANZAPINE RBX does not contain gluten, sucrose, glucose or colouring agents.

#### **Australian Registration Numbers**

2.5 mg - AUST R 157856

5 mg - AUST R 157853

7.5 mg - AUST R 157860

10 mg - AUST R 157859

#### **Sponsor**

OLANZAPINE RBX is supplied in Australia by:

Sun Pharma ANZ Pty Ltd

12 Waterloo Road

Macquarie Park Sydney NSW 2113

Australia

customerservice.aus@sunpharma.com

Tel: 1800 726 229

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