

## OZIN ODT™ 5, 10, 15 & 20

Olanzapine orally disintegrating tablets

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions people ask about OZIN ODT.

It does not contain all the available information. It does not take the place of talking with your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking OZIN ODT 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 this medicine.**

You may need to read it again.

#### What OZIN ODT is used for

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

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

OZIN 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. OZIN 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.

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 OZIN ODT for another reason.

**Always ask your doctor if you need more information.**

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

OZIN 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 you take it

**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 OZIN ODT:**

- **if you have had an allergic reaction to any type of OZIN ODT 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 you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.**

**Do not take OZIN ODT after the use by (expiry) date printed on the pack has passed.**

It may have no effect at all or an unexpected effect if you take it after the expiry date.

**Do not take OZIN ODT if the packaging is torn or shows signs of tampering.**

**Do not use it to treat any other complaints unless your doctor tells you to.**

**Do not give this medicine to anyone else.**

*Before you start to take it:*

**Tell your doctor or pharmacist if:**

- you have had an allergic reaction to any medicine which you have taken previously to treat your current condition; or
- you have allergies to any other substances, such as foods, preservatives or dyes.

**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; or
- 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, OZIN ODT is not recommended for use during pregnancy. If there is a need to consider OZIN ODT during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

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

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

**Tell your doctor if you suffer from phenylketonuria** (because OZIN ODT orally disintegrating tablets contain aspartame).

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

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

**Tell your doctor if you smoke.**

Smoking may affect OZIN ODT or may affect how it works.

*Taking other medicines:*

**Tell your doctor or pharmacist 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 OZIN 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 depression;
- carbamazepine, a medicine used for mood stabilisation and to treat epilepsy;
- other centrally acting medicines (e.g. tranquillisers);
- ciprofloxacin, a medicine used to treat bacterial infections;
- medicines that lower blood pressure;
- medicines used for Parkinson's disease; or
- medicines that can change the heart's electrical activity or make it more likely to change.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

**If you have not told your doctor or pharmacist about any of the above, tell them before you take any OZIN ODT.**

#### How to take it

**Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

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

*How much to take:*

Your doctor will tell you how many OZIN ODT 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 and when to take it:*

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

OZIN ODT orally disintegrating tablets break easily, so you should handle them carefully.

Put the OZIN ODT 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 OZIN ODT 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.

**Do not place the OZIN ODT orally disintegrating tablet in cola drinks.**

**OZIN ODT orally disintegrating tablets should be taken once a day as advised by your doctor.**

Take your prescribed dose at the same time each day.

OZIN ODT orally disintegrating tablets can be taken with or without food.

*How long to take it:*

**Do not stop taking OZIN ODT just because you feel better. It is important that you do NOT stop taking OZIN 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 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 13 11 26 for Australia) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much OZIN ODT. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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

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**While you are taking it**

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*Things you must do:*

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

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

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking OZIN ODT.**

**If you go into hospital, please let the medical staff know you are taking OZIN ODT.**

**If you become pregnant while taking OZIN ODT, 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 OZIN ODT.

- 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 give OZIN ODT to anyone else, even if they have the same condition as you.**

Your doctor has prescribed OZIN ODT for you and your condition.

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

**Do not stop taking OZIN ODT, or lower the dosage, without checking with your doctor.**

*Things to be careful of*

**Be careful driving or operating machinery until you know how OZIN ODT affects you.**

OZIN ODT may cause drowsiness in some people.

**Be careful when drinking alcohol while taking OZIN ODT.**

The effects of alcohol could be made worse while taking OZIN ODT.

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

**If OZIN 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.**

OZIN 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.**

OZIN ODT may affect the way your body reacts to temperature changes

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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 OZIN ODT.**

Your doctor may then decide to adjust the dose of OZIN ODT you are taking.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

**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; or
- 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 OZIN 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 OZIN ODT.

**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 heartbeat;
- 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; or
- 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; or
- 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 OZIN ODT:

#### **Elderly patients with dementia-related psychosis**

Elderly patients with dementia-related psychosis may notice the following side effects:

- unusual manner of walking;
- falls;
- pneumonia; or
- 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.

#### **OZIN ODT in combination with lithium or valproate**

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

- tremors; or
- 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.**

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#### **After taking it**

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##### **Storage**

**Keep your OZIN ODT orally disintegrating tablets in the blister foil until it is time to take them.**

If you take OZIN ODT out of the blister foil they will not keep well.

**Keep your orally disintegrating tablets in a cool, dry place where the temperature stays below 25°C. OZIN ODT orally disintegrating tablets should be stored in the original package.**

**Do not store OZIN ODT or any other medicine in the bathroom or near a sink.**

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

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 OZIN ODT or you find that the tablets have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.**

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#### **Product description**

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##### **What it looks like**

OZIN ODT\* 5, 10, 15 & 20 (containing olanzapine 5 mg, 10 mg, 15 mg & 20 mg) orally disintegrating tablets are supplied in pack sizes of 7 and 28 tablets in blister packs.

**OZIN ODT 5:** Yellow coloured, circular, flat faced beveled edge tablets debossed with 'C' on one side and '51' on the other side.

**OZIN ODT 10:** Yellow coloured, circular, flat faced beveled edge tablets debossed with 'C' on one side and '52' on the other side.

**OZIN ODT 15:** Yellow coloured, circular, flat faced beveled edge tablets debossed with 'C' on one side and '53' on the other side.

**OZIN ODT 20:** Yellow coloured, circular, flat faced beveled edge tablets debossed with 'C' on one side and '54' on the other side.

\*Some of these presentations and pack sizes may not be marketed.

##### **Ingredients**

###### **Active ingredient**

Olanzapine

###### **Other ingredients**

- mannitol;
- polacrillin potassium;
- crospovidone;
- microcrystalline cellulose;
- aspartame;
- colloidal anhydrous silica;
- sodium stearyl fumarate; and
- (SJ95) artificial pineapple FL SD #883.

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#### **Sponsor/Marketing Authorisation Holder**

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