

ZYPINE®; ZYPINE® ODT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking ZYPINE?

ZYPINE contains the active ingredient olanzapine. It helps to correct chemical imbalances in the brain, which may cause mental illness.

For more information, see Section [1. Why am I using ZYPINE?](#) in the full CMI.

2. What should I know before I take ZYPINE?

Do not use if you have ever had an allergic reaction to olanzapine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take ZYPINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZYPINE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take ZYPINE?

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.

- More instructions can be found in Section [4. How do I take ZYPINE?](#) in the full CMI.

5. What should I know while taking ZYPINE?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using ZYPINE.
- Tell your doctor if you become pregnant while taking ZYPINE.
- Keep all of your doctor's appointments so that

	<p>your progress can be checked.</p>
Things you should not do	<ul style="list-style-type: none"> • Do not stop taking your medicine, or change the dosage, without first checking with your doctor. • Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how ZYPINE affects you. ZYPINE may cause drowsiness in some people.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol. The effects of alcohol could be made worse while taking ZYPINE.
Looking after your medicine	<ul style="list-style-type: none"> • Keep your medicine in a cool dry place where the temperature stays below 25°C.

- Keep this medicine where children cannot reach it.

For more information, see Section [5. What should I know while taking ZYPINE?](#) in the full CMI.

6. Are there any side effects?

Like other medicines, ZYPINE may cause some unwanted side effects. These are likely to vary from patient to patient, although not everybody gets them. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need urgent medical attention.

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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ZYPINE®; ZYPINE® ODT

Active ingredient(s): Olanzapine

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZYPINE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZYPINE.**

Where to find information in this leaflet:

- [1. Why am I taking ZYPINE?](#)
- [2. What should I know before I take ZYPINE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take ZYPINE?](#)
- [5. What should I know while taking ZYPINE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking ZYPINE?

ZYPINE contains the active ingredient olanzapine. Olanzapine belongs to a group of medicines called antipsychotics. It helps by correcting chemical imbalances in the brain, which may cause mental illness.

ZYPINE is used to treat:

- Symptoms of schizophrenia and related psychoses

- Acute manic episodes associated with Bipolar I Disorder (as a short-term treatment) with ZYPINE alone or in combination with lithium or valproate.
- 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.

ZYPINE may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may have prescribed ZYPINE for another reason.

Ask your doctor if you have any questions about why ZYPINE has been prescribed for you.

2. What should I know before I take ZYPINE?

Warnings

Do not take ZYPINE if:

- **you have an allergy to:**
 - any medicine containing olanzapine
 - any of the ingredients listed at the end of this leaflet

- any other similar medicines (such as medicines of the same class or with a similar structure, as per PI).

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

- Always check the ingredients to make sure you can use this medicine.
- **the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.**

If you take this medicine after the expiry date has passed it may not work as well. If it has expired or is damaged, return it to your pharmacist for disposal.

- **you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

- **you are breastfeeding.**

The active ingredient in Olanzapine passes into breast milk (if applicable) and there is possibility that your baby maybe affected.

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

Check with your doctor if you:

- have had an allergic reaction to any medicine which you have taken previously to treat your current condition.
- have any other medical conditions, especially the following:
 - 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
 - lipid alterations such as high blood fat values (cholesterol and triglycerides)
 - 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 buildup 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

- DRESS, a severe drug reaction to olanzapine, with a combination of three or more of the following: rash, eosinophilia (higher number of a group of white blood cells), fever, swollen lymph nodes or inflammation of liver, kidney, lung, or heart
- tardive dyskinesia, a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs
- Akathisia, a subjective feeling of restlessness and difficulty sitting still
- sleep apnoea, a sleep disorder where a person has pauses in breathing or periods of shallow breathing during sleep
- elderly with dementia- related psychosis
- previously had a stroke or transient ischaemic attack (mini- stroke) or if you have high blood pressure.

Tell your doctor if

- you will be in a hot environment or do a lot of vigorous exercise. ZYPINE may make you sweat less, causing your body to overheat.
- you smoke. Smoking may affect ZYPINE or may affect how it works.
- you suffer from lactose intolerance (because ZYPINE tablets contain lactose).
- you suffer from phenylketonuria (because ZYPINE ODT contain aspartame).

- you have allergies to any medicines, foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you start taking ZYPINE.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Like most antipsychotic medicines, ZYPINE are not recommended for use during pregnancy.

Newborn babies of mothers taking antipsychotic drugs (including ZYPINE) 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 ZYPINE 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 breastfeed.

It is recommended that you do not breastfeed while taking ZYPINE.

Children

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

3. What if I am taking other medicines?

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

Some medicines may interfere with ZYPINE and affect how it works. These include:

- medicines used to treat a fast or irregular heartbeat (arrhythmia)
- medicines taken for anxiety or to help you sleep
- medicines taken for depression
- carbamazepine, a medicine used for mood stabilization 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 can change the heart's electrical activity or make it more likely to change

- activated charcoal.

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

You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZYPINE.

4. How do I take ZYPINE?

How much to take

Your doctor will tell you how much ZYPINE 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 to find the appropriate dose for your condition.

A lower starting dose may be prescribed for elderly patients over the age of 65 years.

When to take

ZYPINE should be taken once a day as advised by your doctor.

Take your prescribed dose at the same time each day.

Taking it at the same time each day will have the best effects. It will also help you remember when to take it.

ZYPINE can be taken with or without food.

How to take

ZYPINE tablets:

ZYPINE tablets should be swallowed whole with a glass of water.

ZYPINE ODT:

ZYPINE ODT break easily, so you should handle them carefully.

Do not handle the ZYPINE ODT with wet hands as the tablets may breakup.

The ZYPINE ODT can be taken two ways:

- Directly into your mouth
- In a drink

To take ZYPINE ODT directly into your mouth:

- 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 coloured backing.**
- 3. Gently push the tablet out.**
- 4. Put the tablet in your mouth. It will dissolve directly in your mouth, so that it can be easily swallowed.**

To take a tablet in a drink:

You can also place the 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.

ZYPINE ODT should not be place in cola drinks.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

This medicine helps to control your condition, but it does not cure it. It is important to keep taking your medicine even if you feel well.

It is important that you do NOT stop taking ZYPINE unless your doctor tells you.

If you forget to take ZYPINE

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 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 have taken too much ZYPINE

If you think that you or anyone else has taken too much ZYPINE, urgent medical attention may be needed.

If you have taken too much ZYPINE, the most common signs are fast heartbeat, agitation/aggression, difficulty speaking, uncontrollable movements and sleepiness (sedation).

If you think that you have used too much ZYPINE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**Australia telephone 13 11 26**) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking ZYPINE?

Things you should do

- It is important that you remember to take ZYPINE daily and at the dose prescribed by your doctor.
- Tell all doctors, dentists and pharmacists who are treating you that you are taking ZYPINE.
- While you are taking ZYPINE, tell your doctor or pharmacist before you start any new medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
It may affect other medicines used during surgery.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.
It may interfere with the results of some tests.

Tell your doctor immediately if you become pregnant while taking ZYPINE.

- Keep all your doctor's appointments so that your progress can be checked.
- Your doctor should monitor your weight while you are taking ZYPINE.
- 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.**
- **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.

All thoughts of suicide or violence must be taken seriously.

Things you should not do

- Do not stop taking ZYPINE, or lower the dosage, even if you are feeling better, without checking with your doctor.
- Do not give ZYPINE to anyone else, even if their symptoms seem similar or they have the same condition as you. Your doctor has prescribed ZYPINE for you and your condition.

Things you should be careful of

- **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.**

ZYPINE 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.**

ZYPINE may affect the way your body reacts to temperature changes.

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZYPINE affects you.

ZYPINE may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

The effects of alcohol could be made worse while taking ZYPINE.

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

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Like other medicines, ZYPINE 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 ZYPINE. 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 ZYPINE you are taking.

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 ZYPINE for a few days.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• drowsiness• unusual tiredness or weakness• fever• restlessness or difficulty sitting still• increased appetite, weight gain• constipation, bloating• dry mouth	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● swelling of your hands, feet and ankles ● aching joints ● nose bleeds ● dizziness, confusion, forgetfulness ● speech disorder ● sleepwalking ● sleep eating 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 	<p>Tell your doctor as soon as possible if you notice any of these serious side effects. You may need medical attention.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 ● lipid alterations, such as high blood fat values (cholesterol and triglycerides) ● 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 	

Serious side effects	What to do
<ul style="list-style-type: none"> • unusual hair loss or thinning 	

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> • 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. You may need urgent medical attention or hospitalisation.</p>

Very serious side effects	What to do
<ul style="list-style-type: none"> ● nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching ● 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 ● sudden decrease in body temperature, intense trembling, lethargy, confusion, slow heartbeat and slow breathing ● sharp chest pain, coughing of blood, or 	

Very serious side effects	What to do
<p>sudden shortness of breath</p> <ul style="list-style-type: none"> ● 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 following additional side effects may occur in some groups of people taking ZYPINE.

Elderly patients with dementia-related psychosis

- 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.

In combination with lithium or valproate

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

- tremors
- speech disorder
- dry mouth
- increase appetite
- weight gain

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 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. Most of these side effects are very rare. You may not experience any of them. Your doctor has weighed the risks of using

this medicine against the benefits they expect it will have for you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ZYPINE tablet contains

Active ingredient (main ingredient)	olanzapine
Other ingredients	• crospovidone

(inactive ingredients)	<ul style="list-style-type: none"> • lactose monohydrate • magnesium stearate • maize starch • OPADRY AMB OY-B-28920 (ID: 10274) • pregelatinised maize starch
Potential allergens	<ul style="list-style-type: none"> • sugars as lactose • sulfites

- Each ZYPINE 2.5 mg tablet contains 2.5 mg of olanzapine.
- Each ZYPINE 5 mg tablet contains 5 mg of olanzapine.
- Each ZYPINE 7.5 mg tablet contains 7.5 mg of olanzapine.
- Each ZYPINE 10 mg tablet contains 10 mg of olanzapine.

What ZYPINE ODT contains

Active ingredient (main ingredient)	olanzapine
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • mannitol • microcrystalline cellulose • guar gum • crospovidone • magnesium stearate

	<ul style="list-style-type: none"> • colloidal anhydrous silica • aspartame • sodium lauryl sulfate
Potential allergens	<ul style="list-style-type: none"> • aspartame • phenylalanine • sulfites • gluten

- Each ZYPINE ODT 5 mg orally disintegrating tablet contains 5 mg of olanzapine.
- Each ZYPINE ODT 10 mg orally disintegrating tablet contains 10 mg of olanzapine.
- Each ZYPINE ODT 15 mg orally disintegrating tablet contains 15 mg of olanzapine.
- Each ZYPINE ODT 20 mg orally disintegrating tablet contains 20 mg of olanzapine.

Do not take this medicine if you are allergic to any of these ingredients.

What ZYPINE tablets looks like

- **2.5 mg** - approximately 7.0 mm normal convex, white film coated tablets debossed "OZ" over "2.5" on one side and "G" on the other side (AUST R 154620).
- **5 mg** - approximately 8.0 mm normal convex, white film coated tablets debossed "OZ" over "5" on one side and "G" on the other side (AUST R 154624).
- **7.5 mg** - approximately 9.0 mm normal convex, white film coated tablets debossed "OZ" over "7.5" on one side and "G" on the other side (AUST R 154621).

- **10 mg** - approximately 10.2 mm normal convex, white film coated tablets debossed "OZ" over "10" on one side and "G" on the other side (AUST R 154617).

Each blister pack contains 28 tablets.

What ZYPINE ODT looks like

- **5 mg** - Light yellow to yellow coloured, plain to mottled, round, flat faced, bevelled edged tablets debossed with "M" on one side and "OE1" on other side (AUST R 175773).
- **10 mg** - Light yellow to yellow coloured, plain to mottled, round, flat faced, bevelled edged tablets debossed with "M" on one side and "OE2" on other side (AUST R 175775).
- **15 mg** - Light yellow to yellow coloured, plain to mottled, round, flat faced, bevelled edged tablets debossed with "M" on one side and "OE3" on other side (AUST R 189670).
- **20 mg** - Light yellow to yellow coloured, plain to mottled, round, flat faced, bevelled edged tablets debossed with "M" on one side and "OE4" on other side (AUST R 189673).

Each blister pack contains 28 orally disintegrating tablets.

Who distributes ZYPINE

Alphapharm Pty Ltd trading as Viatris
Level 1, 30 The Bond
30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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