

NEW ZEALAND CONSUMER MEDICINE INFORMATION

ZYPINE

Olanzapine Tablets 2.5 mg, 5 mg & 10 mg



What is in this leaflet

Please read this leaflet carefully before you start taking ZYPINE.

This leaflet answers some common questions about ZYPINE.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ZYPINE 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 the medicine. You may need to read it again.

What ZYPINE is used for

ZYPINE is used to treat a condition with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this condition may also feel depressed, anxious or tense.

ZYPINE is also used to treat a condition 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. It is also a mood stabiliser that prevents further occurrences of the disabling high and low (depressed) extremes of mood associated with this condition.

ZYPINE contains the active ingredient olanzapine. It belongs to a group of medicines called antipsychotics. These medicines help to correct chemical imbalances in the brain, which may cause mental health problems.

Your doctor may have prescribed it for another reason.

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

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

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take ZYPINE

When you must not take it:

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

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.

Do not take this medicine if you have glaucoma (increased pressure in your eye).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged,

return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- prostate problems
- high blood sugar, diabetes or a family history of diabetes
- kidney or liver disease
- blood disorders, with a reduced number of white or red blood cells
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions
- epilepsy, seizures or fits
- tardive dyskinesia, a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs
- heart disease
- disease of the blood vessels in the brain, including stroke
- paralytic ileus, a condition where the small bowel does not work properly and causes blockage
- breast cancer or a family history of breast cancer
- Parkinson's disease
- blood clots or a family history of blood clots
- dementia
- lung infections

- temporarily stopping breathing during sleep
- menstrual irregularities.

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

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

The general condition of your new-born baby might be affected by the medicine. If your baby has been exposed to this medicine during the last three months of pregnancy it may suffer withdrawal symptoms such as trouble with breathing, feeding difficulties, stiff or floppy muscles, tremor, jitteriness, irritability and sleepiness. These symptoms may need urgent medical attention. If your new-born baby has any of these symptoms, contact your doctor immediately.

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

It is recommended that you do not breast-feed while taking this medicine, as small amounts of olanzapine can pass into breast milk.

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

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking ZYPINE.

Some medicines may interfere with ZYPINE. These include:

- medicines taken for anxiety or to help you sleep (tranquillisers)
- medicines used for Parkinson's disease

- medicines used to treat a fast or irregular heart beat (arrhythmia)
- medicines taken for depression (e.g. fluoxetine, fluvoxamine)
- carbamazepine, a medicine used for mood stabilisation and to treat epilepsy
- ciprofloxacin, a medicine used to treat bacterial infections.

These medicines may be affected by ZYPINE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Smoking may affect ZYPINE or may affect how it works.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ZYPINE

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

They may differ from the information contained in this leaflet.

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

How much to take

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 of 5 mg to 20 mg per day.

Your doctor may increase or decrease your dose in order to find the appropriate dose for you.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

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

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you. It may take several days to some weeks until your condition improves.

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

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, and 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.

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.

While you are taking ZYPINE

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ZYPINE.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this 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 become pregnant while taking this medicine, tell your doctor immediately.

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

Your doctor may do some tests for blood lipid levels and weight monitoring from time to time 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 years old, your doctor may measure your blood pressure from time to time.

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

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

If you stop taking it suddenly, you may have unwanted side effects such as:

- shaking
- sweating
- being unable to sleep
- feeling anxious
- feeling or being sick (nausea or vomiting).

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how ZYPINE affects you.

This medicine may cause drowsiness and somnolence in some people.

Be careful when drinking alcohol while you are taking this medicine.

The effects of alcohol may be worse. Your doctor may suggest you avoid alcohol while you are being treated with ZYPINE.

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 you are outdoors, wear protective clothing and at least a 15+ sunscreen.

This medicine 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.

This medicine may affect the way your body reacts to temperature changes.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ZYPINE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include rapid beating of the heart, agitation/aggression, shaking, difficulty speaking, unusual movements (especially of the face and tongue), excessive production of saliva, sleepiness, lack of coordination, loss of appetite and reduced levels of consciousness.

Side effects

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

This medicine helps most people with mental disorders, but it may

have unwanted side effects in a few people.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- weight gain
- drowsiness
- constipation
- dry mouth
- increased appetite
- swelling of your hands, feet and ankles
- unusual tiredness, or weakness
- dizziness
- restlessness or difficulty sitting still
- joint pain
- fever
- nose bleeds
- excessive production of saliva
- stuttering.

Tell your doctor as soon as possible if you notice any of the following:

- symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) which occur more quickly than normal
- slow heart beat
- prolonged and/or painful erection or erection problems
- decreased libido (male and female)
- unusual secretion of breast milk
- breast enlargement
- symptoms of high sugar levels in the blood (including passing large amounts of urine, excessive thirst, having a dry mouth, increased appetite with

weight loss, tiredness and weakness). These may indicate the onset or worsening of diabetes

- reaction following abrupt discontinuation (e.g. profuse sweating, nausea or vomiting, shaking, sleep disorders, anxiety)
- absence of menstrual periods and changes in the regularity of menstrual periods.
Tell your doctor if your monthly periods are absent for six months or more.
- involuntary passing of urine or difficulty in initiating urination
- unusual hair loss or thinning
- bloating and swelling in the belly area
- change in memory or loss of memory
- sleep walking
- temporality stopping breathing during sleep.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- an allergic reaction (symptoms 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)
- frequent infections such as fever, severe chills, sore throat, swollen lymph nodes 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, light coloured bowel motions, dark coloured urine
- loss of appetite, unexplained weight loss, nausea, vomiting, stomach pain, difficulty breathing, slow heart beat, unusual muscle pain or feeling weak, tired or uncomfortable

- inflammation of the pancreas, causing severe upper stomach pain often with nausea and vomiting
- 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
- sharp chest pain, coughing of blood, or sudden shortness of breath
- muscle pain, muscle weakness
- heart palpitations and dizziness, which may lead to collapse
- coma
- arrhythmic heart beat
- heart attack
- sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness heat or swelling in the arms and legs.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some side effects (for example, changes in liver or kidney function, blood cell counts, uric acid levels, cholesterol or triglyceride levels) can only be found when your doctor does tests from time to time to check your progress.

Some people may feel dizzy in the early stages of treatment, especially when getting up from a sitting or lying position. This side effect may pass after taking ZYPINE for a few days.

In addition to the above, elderly patients with dementia-related psychosis may notice the following side effects:

- unusual manner of walking
- falls
- pneumonia

- involuntary passing of urine.

In addition to the above, patients with Parkinson's disease may hallucinate (see, feel or hear things that are not there) or develop worsening symptoms of Parkinson's disease.

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

- tremors
- speech disorder.

Tell your doctor as soon as possible if you notice any of the above side effects and they worry you.

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

Do not be alarmed by those lists of possible side effects. You may not experience any of them.

After taking ZYPINE

Storage

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

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ZYPINE, or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ZYPINE 2.5 mg tablets are normal convex, white film coated tablets debossed "OZ" over "2.5" on one side and "G" on the other, 7 mm in diameter.

ZYPINE 5 mg tablets are normal convex, white film coated tablets debossed "OZ" over "5" on one side and "G" on the other, 8 mm in diameter.

ZYPINE 10 mg tablets are normal convex, white film coated tablets debossed "OZ" over "10" on one side and "G" on the other, 10.2 mm in diameter.

Ingredients

Active ingredient:

ZYPINE contains olanzapine as the active ingredient.

Inactive ingredients:

Each ZYPINE tablet also contains:

- lactose
- maize starch
- pregelatinised maize starch
- crospovidone
- magnesium stearate
- Opadry White OY-B-28920 (contains polyvinyl alcohol, titanium dioxide, talc, soya lecithin and xanthan gum).

Sulfites may be present in this product in trace amounts.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

ZYPINE is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,

Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 579 811

Date of Information

15 April 2021

(Based on datasheet dated 15 April 2021)