

APO-Ziprasidone

Contains the active ingredient ziprasidone hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet, ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine 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 this medicine is used for

The name of your medicine is APO- Ziprasidone. It contains the active ingredient ziprasidone (as ziprasidone hydrochloride).

It is used to treat schizophrenia and bipolar disorder.

Ziprasidone belongs to a group of medicines called atypical antipsychotics/neuroleptics.

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

Your doctor may have prescribed it for another reason.

Ziprasidone is available only with a doctor's prescription.

Schizophrenia

Schizophrenia is a mental illness. It varies from person to person, but can involve:

- hallucinations: the person sees, hears, feels, smells or tastes something that is not actually there; most commonly a person may hear voices
- delusions: a delusion is a false belief held by a person which is not held by others of the same cultural background

- disturbed or disorganised thinking
- poor memory and concentration
- loss of emotion and expression
- loss of motivation and energy
- difficulty interacting with others, leading to social isolation.

Bipolar disorder

Bipolar disorder is a mental illness where a person cycles through:

- 'manic' phases - with symptoms such as over-activity, irritability, elation and limited need for sleep
- 'depressive' phases - with symptoms such as depressed mood, anxiety, difficulty making decisions, difficulty concentrating and hopelessness.

How it works

Schizophrenia

Researchers do not know exactly what causes schizophrenia, but they do know that many people with it have high levels of some brain chemicals - including dopamine and serotonin.

Ziprasidone is thought to work by helping to correct the imbalance of these chemicals, in turn, reducing the symptoms of schizophrenia.

Research has found ziprasidone can help reduce:

- hallucinations
- delusions
- confused thoughts
- social withdrawal
- lack of motivation

Ziprasidone does not cure schizophrenia, but it can help manage the symptoms and help prevent further episodes.

Taking antipsychotic/neuroleptic medicines like ziprasidone can also allow you to try psychological therapies when recommended by your doctor. These may further help you manage your schizophrenia.

Bipolar disorder

Research has shown that there is a chemical imbalance in the brain in patients with bipolar disorder.

Ziprasidone does not cure bipolar disorder. It is used as a short-term treatment for the manic phases. It is not used to treat the depressive phases of bipolar disorder.

Controlling the manic phase of bipolar disorder with medicine can also allow you to try psychological therapies when recommended by your doctor.

Elderly patients

Ziprasidone is not recommended for the treatment of elderly patients with dementia-related psychosis.

It should be used with caution in elderly patients with risk factors for stroke.

Use in children

Ziprasidone is not recommended for children under 18 years of age as there is not enough information on its effects in this age group.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing ziprasidone
- 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 or have had any of the following medical conditions:

- a recent heart attack
- heart failure that is not well - controlled
- abnormal heart rhythm
- any condition requiring medication to control your heart rhythm.

Do not take this medicine if you are taking any other medications known to lengthen your heart rhythm.

Do not take this medicine if you are pregnant.

Like most atypical antipsychotic/ neuroleptic medicines, ziprasidone is not recommended for use during pregnancy.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

For women of child-bearing age, an appropriate method of contraception is recommended.

Do not breastfeed if you are taking this medicine.

Do not take ziprasidone whilst breastfeeding until you and your doctor have discussed the risks and benefits involved. It may pass into breastmilk

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:

- irregular heart rate
- a condition requiring other drugs to control your heart rhythm
- any heart or blood vessel problems
- low blood levels of potassium or magnesium
- a condition that may give you low blood pressure
- seizures (fits)
- liver problems
- blood sugar level problems, e.g. diabetes

- you are 65 years of age or over and have a condition known as 'dementia-related psychosis'
- if you have ever suffered or suffer from a condition called deep vein thrombosis (DVT). DVT is the formation of blood clots in one of the deep veins within the body, e.g. the leg or pelvis. The symptoms of DVT are pain and swelling in your legs. Sometimes the blood clot may break away from its original location and travel to the lungs. This condition is called pulmonary embolism (PE). Symptoms of PE may include sharp chest pain, shortness of breath or you may cough up blood

Tell your doctor if you have ever had any of the following reactions to this type of medicine:

- Neuroleptic Malignant Syndrome (NMS) – symptoms include sudden fever, fast breathing, blood pressure changes, sweating, confusion, muscle stiffness and drowsiness or sleepiness
- Tardive Dyskinesia (TD) – symptoms include unusual movements (mainly of the face and tongue), or uncontrollable twitching or jerking of the arms and legs

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

Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

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

Some medicines and ziprasidone may interfere with each other. These include:

- lithium, used to treat bipolar disorders
- medicines which act on the central nervous system (CNS), such as triptans, antipsychotics and antidepressants
- alcohol
- medicines used to control (lengthen or shorten) heart rhythm
- ketoconazole, used to treat fungal infections
- carbamazepine, used to treat epilepsy
- rifampicin, an antibiotic used for the treatment of tuberculosis
- a type of herbal medicine to treat depression called St John's Wort (*Hypericum perforatum*)

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

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

Other medicines not listed above may also interact with ziprasidone.

How to take this medicine

Follow carefully all directions given to you by your doctor.

Their instructions may be different to the information in this leaflet.

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

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

Schizophrenia

The usual starting dose is one 40 mg capsule taken twice daily with food.

Your doctor may increase your dose up to one 80 mg capsule twice daily with food.

Allow at least 48 hours between changes to your dose unless otherwise instructed by your doctor.

You may reach the maximum dose of one 80 mg capsule twice daily with food on the third day from the start of your treatment.

Bipolar disorder

The usual starting dose is one 40 mg capsule twice daily with food.

Your doctor may adjust your dose up to one 80 mg capsule twice daily with food.

You may reach the maximum dose of one 80 mg capsule twice daily with food on the second day from the start of your treatment.

How to take it

Swallow the capsule(s) whole with a glass of water.

When to take it

Take your capsule(s) with food, so in the morning with breakfast and in the evening with your evening meal.

You need to take ziprasidone with food because it helps your body absorb the medicine better. If you do not take it with food, the medicine may have less effect.

Take this medicine at the same times each day. Taking it at the same times each day will have the best effect and will also help you remember when to take it.

How long to take it for

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

If you forget to take it

If it is almost time to take 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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you

think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much ziprasidone, you may feel drowsy and show signs of tremor and uncontrollable movements of the tongue, jaw, arms and legs.

While you are taking this medicine

Things you must do

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

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 or start to breastfeed while taking this medicine, tell your doctor immediately.

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.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Talk to your doctor or mental health professional if you have thoughts or talk about death, suicide or self-harm.

These may be signs of changes or worsening in your mental illness.

Things you must not do

Do not take this medicine 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 without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

If you feel drowsy or sleepy while taking ziprasidone, do not drive or operate machinery, or do things that could be dangerous if you are not alert.

Make sure you know how you react to ziprasidone before you drive a car, operate machinery or do anything else that could be dangerous if you are not alert.

Ziprasidone may also cause falls resulting in fractures or other injuries in some people.

Be careful when drinking alcohol while taking ziprasidone.

Combining ziprasidone and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest you avoid alcohol while you are being treated with ziprasidone.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

- headache
- feeling sick (nausea)
- vomiting

- sleepiness
- difficulty sleeping
- dizziness on standing up, especially when getting up from a sitting or lying position
- dry mouth
- too much saliva
- indigestion
- constipation
- diarrhoea
- restlessness
- muscle stiffness
- blurred vision
- palpitations
- weakness or loss of strength
- drowsiness
- dizziness, blackouts or feeling faint
- anxiety or agitation
- loss of control of your bladder

- unusual secretion of breast milk
- persistent painful erection of the penis without sexual arousal
- male sexual dysfunction

The above list includes the more common side effects of your medicine.

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

- any worm-like movements of the tongue
- any other uncontrolled movements of the tongue, mouth, cheeks or jaw
- any uncontrolled movements spreading to the arms and legs
- sleepwalking
- eating during sleepwalking
- breathing stopping and starting while sleeping. Symptoms can be loud or frequent snoring, silent pauses in breathing, choking or gasping sounds

Some of these are symptoms of a condition called Tardive Dyskinesia (TD).

The above list includes serious side effects that may require medical attention.

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

- convulsions, fit or seizures
- trembling and shaking of the hands and fingers
- shuffling walk and stiffness of the arms and legs
- sudden uncontrollable muscle spasms in the eyes, head, neck and body
- symptoms of a condition called Neuroleptic Malignant Syndrome (NMS), which include: high fever, fast breathing, stiff muscles and confusion, drowsiness or sleepiness

These are very serious side effects and can also occur after you stop taking ziprasidone. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this medicine 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 APO-Ziprasidone looks like

20 mg capsules:

Blue/White size '4' hard gelatin capsules imprinted in black ink with "CL62" on the cap and "20 mg" on the body; filled with pale pink coloured powder. AUST R 201046. AUST R 201057.

40 mg capsules:

Blue/Blue size '2' hard gelatin capsules imprinted in black ink with "CL63" on the cap and "40 mg" on the body; filled with pale pink coloured powder. AUST R 201053. AUST R 201058.

60 mg capsules:

White/White size '1' hard gelatin capsules imprinted in black ink with "CL64" on the cap and "60 mg" on the body; filled with pale pink coloured powder. AUST R 201054. AUST R 201059.

80 mg capsules:

Blue/White size '0' hard gelatin capsules imprinted in black ink with "CL65" on the cap and "80 mg" on the body; filled with pale pink coloured powder. AUST R 201055. AUST R 201060.

Available in:

Blister packs of 60 capsules.

Bottles of 300 capsules

Titration Pack: contains 6 capsules available in blister packs (2 × 40 mg capsules, 2 × 60 mg capsules, 2 × 80 mg capsules).
AUST R 201087.

Ingredients

Each capsule contains ziprasidone hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- sodium starch glycollate type B
- macrogol 6000
- lactose monohydrate
- sucrose
- ammonium chloride
- sodium lauryl sulfate
- gelatin (contains sulfites)
- titanium dioxide
- indigo carmine (20 mg, 40 mg and 80 mg capsules only)
- TekPrint SW-9008 black ink

This medicine is gluten-free, tartrazine-free and free of other azo dyes.

Sponsor

Apotex Pty Ltd

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