

Ziprasidone GH

Consumer Medicine Information (CMI) Summary [optional]

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 using Ziprasidone GH?

Ziprasidone GH contains the active ingredient ziprasidone hydrochloride. Ziprasidone GH is used to treat schizophrenia and bipolar disorder. For more information, see Section [1. Why am I using Ziprasidone GH?](#) in the full CMI.

2. What should I know before I use Ziprasidone GH?

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

Talk to your doctor or pharmacist 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 use Ziprasidone GH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ziprasidone GH 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 use Ziprasidone GH?

- The usual starting dose is one 40 mg capsule taken twice daily with food.
- Take your capsule(s) with food, i.e. in the morning with breakfast and in the evening with your evening meal.

More instructions can be found in Section [4. How do I use Ziprasidone GH?](#) in the full CMI.

5. What should I know while using Ziprasidone GH?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking Ziprasidone GH.• Talk to your doctor or mental health professional if you have thoughts or talk about death, suicide or self-harm.• Check with your doctor if you are pregnant or intend to become pregnant.• Talk to your doctor if you are breastfeeding or intend to breastfeed. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop taking Ziprasidone GH or change the dosage, even if you feel better, without checking with your doctor. |
| 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 Ziprasidone GH affects you.• Ziprasidone GH may cause drowsiness and sleepiness in some people. |
| Drinking alcohol | <ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• Combining Ziprasidone GH 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 GH. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep the capsules in their pack until it is time to take them.• Keep Ziprasidone GH in a cool, dry place where the temperature stays below 30°C. |

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

6. Are there any side effects?

Speak to your doctor if you have any of the following: headache; nausea; vomiting; sleepiness; dry mouth; indigestion; constipation; diarrhoea; muscle stiffness; anxiety; blackouts or feeling faint; restlessness or difficulty sitting still. **Tell your doctor immediately 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. **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of the following:** 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.

This is not a complete list of all possible side effects. 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.

Ziprasidone GH

Active ingredient: ziprasidone hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ziprasidone GH. **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 Ziprasidone GH.**

Where to find information in this leaflet:

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

1. Why am I using Ziprasidone GH?

Ziprasidone GH contains the active ingredient ziprasidone hydrochloride. It belongs to a group of medicines called atypical antipsychotics/neuroleptics.

Ziprasidone GH is used to treat schizophrenia and bipolar disorder.

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, concentrating and hopelessness.

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

Research has found Ziprasidone GH can help reduce:

- hallucinations;
- Delusions;
- confused thoughts;
- social withdrawal;
- lack of motivation.

Ziprasidone GH does not cure schizophrenia, but it can help manage the symptoms and help prevent further episodes. Taking antipsychotic/neuroleptic medicines like Ziprasidone GH 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 GH does not cure bipolar disorder. It is used as a short-term treatment for the manic phases. Ziprasidone GH 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.

Your doctor may have prescribed Ziprasidone GH for another reason.

Ask your doctor or pharmacist if you have any questions about Ziprasidone GH or why Ziprasidone GH has been prescribed for you.

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

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

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

2. What should I know before I use Ziprasidone GH?

Warnings

Do not use Ziprasidone GH if:

- you are allergic to any medicine containing ziprasidone, or any of the ingredients listed at the end

of this leaflet. Always check the ingredients to make sure you can take this medicine. Symptoms of an allergic reaction to Ziprasidone GH may include:

- hives, itching or skin rash;
- shortness of breath, wheezing;
- swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing.
- you have or have had any of the following medical conditions:
 - a recent heart attack;
 - heart failure that is not well-controlled;
 - abnormal rhythm of the heart;
 - any other condition requiring drugs to control your heart rhythm.

Do not take Ziprasidone GH 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.

Check with your doctor if you:

- have any allergies to:
 - any other medicines;
 - any other substances such as foods, preservatives or dyes.
- have or have had any other medical conditions, especially the following:
 - irregular heart rate;
 - a condition requiring other drugs to control the heart rhythm;
 - any heart or blood vessel problems;
 - low blood levels of potassium or magnesium;
 - a condition that may give you low blood pressure;
 - a history of seizures (fits);
 - liver problems;
 - blood sugar level problems e.g., diabetes;
 - headache;
 - nausea;
 - vomiting;
 - blurred vision;
 - muscle weakness;
 - if 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.
 - breathing stops and starts while sleeping.

- 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) - unusual movements (mainly of the face and tongue), or uncontrollable twitching or jerking of the arms and legs.
- take any medicines for any other condition.

If you have some medical conditions, you may not be able to take Ziprasidone GH, or your doctor may need to adjust your medicines.

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

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

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

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

If you become or plan to become pregnant while taking Ziprasidone GH your doctor will discuss the benefits and risks of taking it.

Babies exposed to antipsychotic drugs (including Ziprasidone GH) during the third trimester of pregnancy are at risk of experiencing agitation, abnormal muscle tone, tremor, somnolence, breathing problems, difficulty in feeding and/or withdrawal symptoms after being born.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Ziprasidone GH is not recommended while you are breastfeeding. It is thought that low levels of Ziprasidone GH passes into breast milk.].

3. What if I am taking other medicines?

Some medicines may interfere with Ziprasidone GH and affect how it works.

Your doctor may need to give you different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines;
- all medicines you buy over the counter from a pharmacy or supermarket;
- all complementary and alternative therapies;
- any supplements or herbal remedies you buy from a health food shop;

- a type of herbal medicine to treat depression called St John's Wort (*Hypericum perforatum*);
- any illicit drugs.

Tell your doctor or pharmacist if you are taking medicines for any of the following conditions:

- Parkinson's disease;
- fast or irregular heart rhythms;
- insomnia (unable to fall asleep or stay asleep;)
- anxiety;
- depression or mood swings;
- pain - especially any narcotic pain killers;
- epilepsy or mood disorders - especially carbamazepine;
- fungal infections - especially ketoconazole;
- rifampicin an antibiotic used for the treatment of tuberculosis.

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

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

4. How do I use Ziprasidone GH?

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

These may differ from the information contained in this leaflet.

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

How much to take

How much Ziprasidone GH you need to take will depend upon your condition.

Schizophrenia

- The usual starting dose is one 40 mg capsule taken twice daily with food.
- Your doctor may increase your dose up to a maximum of 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 a maximum of one 80 mg capsule twice daily with food. This dose may be reached on the second day from the start of your treatment.

How long to take Ziprasidone GH

Keep taking Ziprasidone GH for as long as your doctor recommends, even if you feel better.

If you keep taking Ziprasidone GH as recommended, there is less chance of your symptoms returning.

When to take Ziprasidone GH

- 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 GH with food because it helps your body absorb the medicine much better. If you do not take with food, the medicine may have less effect.

How to take Ziprasidone GH

- Swallow the capsules whole with a full glass of water.

If you forget to take Ziprasidone GH

Ziprasidone GH should be used regularly at the same time each day.

If you miss your dose at the usual time and 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 it as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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 have trouble remembering to take your capsules, ask your doctor or pharmacist for help.

If you take too much Ziprasidone GH

If you take too much Ziprasidone GH, you may feel slightly drowsy and show signs of tremor and uncontrollable movements of the tongue, jaw, arms and legs. High and low blood pressure, diarrhoea, a fast heart rate may also be experienced. Your lungs might fail to breathe properly which can result in a build-up of carbon dioxide in the body.

If you think that you or anyone else may have taken too much Ziprasidone GH, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**); 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 using Ziprasidone GH?

Things you should do

- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking Ziprasidone GH.
- Remind any doctor, dentist or pharmacist you visit that you are taking Ziprasidone GH.
- Keep all of your doctor's appointments so that your doctor can check your progress. Your doctor will check your progress and may want to take some blood tests from time to time. This helps 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.

Call your doctor straight away if you:

- become pregnant while taking Ziprasidone GH.

Things you should not do

- **Do not stop taking Ziprasidone GH or change the dosage, even if you feel better, without checking with your doctor.**
- Do not take Ziprasidone GH to treat any other complaint unless your doctor tells you to.
- Do not give Ziprasidone GH to anyone else, even if they have the same condition as you.

Driving or using machines

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

Ziprasidone GH may cause drowsiness and sleepiness in some people.

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

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while taking Ziprasidone GH.

Combining Ziprasidone GH 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 GH.

Looking after your medicine

- Keep the capsules in their pack until it is time to take them. If you take the capsules out of the pack they may not keep well.
- Keep Ziprasidone GH in a cool, dry place where the temperature stays below 30°C.

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

Store it in a cool dry place 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.

Keep it where young children cannot reach it.

A locked cupboard at least one and a half metres 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?

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

This medicine has been prescribed to help you, but it may have unwanted side effects in some people.

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.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>Physical problems:</p> <ul style="list-style-type: none"> • 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; • male sexual dysfunction; • In schizophrenia studies of 4-6 weeks duration, the incidence of weight gain in people taking Ziprasidone GH was low and | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These are common side effects of Ziprasidone GH.</p> |

| Less serious side effects | What to do |
|---|------------|
| <p>comparable to those who took a placebo or inactive medicine.</p> <p>Mental or emotional problems:</p> <ul style="list-style-type: none"> • drowsiness or sleepiness; • trouble sleeping; • restlessness or difficulty sitting still; • dizziness, blackouts or feeling faint; • anxiety or agitation; • loss of control of your bladder; • unusual secretion of breast milk. | |

Tell your doctor or pharmacist if you have a persistent painful erection of the penis without sexual arousal.

Serious side effects

| Serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> • 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 stops and starts while sleeping. Symptoms can be loud or frequent snoring, silent pauses in breathing, choking or gasping sounds. <p>These are symptoms of a condition called Tardive Dyskinesia. Tardive Dyskinesia is more likely in people who have been taking Ziprasidone GH or other antipsychotics/neuroleptics medications for a long time. If detected early, it is usually reversible. Your doctor will decide whether to lower your dose or stop the medicine completely.</p> | <p>Tell your doctor immediately if you notice any of these serious side effects.</p> <p>Medical attention may be required.</p> |

Very serious side effects

| Very serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> • 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 • sudden signs of allergy - including skin rash, itching or hives; swelling | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p> |

| Very serious side effects | What to do |
|--|---|
| <p>of the face, lips or tongue, shortness of breath or difficulty breathing (symptoms resembling a condition called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS));</p> <ul style="list-style-type: none"> • pain and swelling in the large veins of your legs or hip; • sharp chest pain, shortness of breath or and coughing up blood. | <p>these serious side effects.</p> <p>These symptoms can also sometimes happen after you stop taking Ziprasidone GH. You may need urgent medical attention or hospitalization,</p> |

Stop taking Ziprasidone GH and contact your doctor immediately or go straight to the Emergency Department at your nearest hospital if you get all of the following at once:

- high fever
- fast breathing
- stiff muscles
- confusion, drowsiness or sleepiness

These are symptoms of a condition called Neuroleptic Malignant Syndrome (NMS).

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 Ziprasidone GH contains

| | |
|---|---|
| Active ingredient (main ingredient) | ziprasidone hydrochloride |
| Other ingredients (inactive ingredients) | Colloidal anhydrous silica Croscarmellose sodium Pregelatinised maize starch Magnesium stearate Gelatin Titanium dioxide |

| | |
|----------------------------|--|
| | Indigo carmine (20 mg, 40 mg and 80 mg capsules) Iron oxide yellow (60 mg capsules only). |
| Potential allergens | Not applicable |

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

What Ziprasidone GH looks like

Ziprasidone GH 20 mg capsules: Size 4 capsule, white body, blue cap. (AUST R 221071).

Ziprasidone GH 40 mg capsules: Size 4 capsules, blue body, blue cap. (AUST R 221096).

Ziprasidone GH 60 mg capsules: Size 3 capsules, ivory body, ivory cap. (AUST R 221079).

Ziprasidone GH 80 mg capsules: Size 2 capsules, white body, blue cap. (AUST R 221089).

Who distributes Ziprasidone GH

Generic Health Pty Ltd

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