

## ZOPICLONE GH

(zopiclone) film coated tablets

### Consumer Medicine Information

#### What is in this leaflet

##### Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about zopiclone. 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 your medicine. You may need to read it again.

#### What Zopiclone GH is used for

Zopiclone GH is used to help people over 18 years of age with sleeping difficulties, also called insomnia. It can help you fall asleep and to reduce the number of times you wake up during the night. It is used for short term treatment (7-14 days) of insomnia.

Your doctor, however, may prescribe Zopiclone GH for another purpose.

##### Ask your doctor if you have any questions about why Zopiclone GH has been prescribed for you.

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

#### Before you take Zopiclone GH

##### When you must not take it

##### Do not take Zopiclone GH if you have:

- been drinking alcohol or you believe that you may have alcohol in your bloodstream;
- sleep apnoea (a condition where you temporarily stop breathing while you sleep);
- myasthenia gravis (a condition in which the muscles become weak and tire easily);
- severe liver problems;
- acute and/or severe lung problems;
- had a stroke;
- ever experienced sleep-walking or other unusual behaviour (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking Zopiclone.

##### Do not take Zopiclone GH as a long term treatment.

##### Do not take zopiclone if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath, or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

##### Do not give Zopiclone GH to children or adolescents.

There is no experience with its use in children or adolescents.

##### Do not take if you are pregnant or intend to become pregnant.

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

discuss the risks and benefits of taking it if you are pregnant.

##### Do not take it if you are breastfeeding or planning to breastfeed.

Zopiclone passes into breast milk and there is a possibility your baby may be affected.

Your doctor will discuss the risks and benefits of using it if you are breastfeeding or planning to breastfeed.

##### Do not take Zopiclone GH after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take Zopiclone GH if the packaging is damaged or shows signs of tampering.

##### Before you start to take it

##### Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet;
- any other substances, such as foods, dyes or preservatives.

##### Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Zopiclone GH is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

##### Tell your doctor if you are breastfeeding or planning to breastfeed.

Your doctor will discuss the risks of taking it if you are breastfeeding or planning to breastfeed.

##### Tell your doctor if you have any problems with your breathing or if you often snore while you are asleep.

Tell your doctor if you have ever been addicted to alcohol or any drug or medicine, or if you have ever suffered from a mental illness. If you have, you may be at risk of getting into a regular pattern or habit of taking Zopiclone GH.

##### Tell your doctor if you ever had a history of sleep-walking or other unusual behaviour (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake after taking Zopiclone GH.

Zopiclone GH may cause sleep walking or other unusual behavior (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake, some of which have been associated with serious injuries and death. The next morning, you may not remember that you did anything during the night. These activities may occur whether or not you drink alcohol or take other medicines that make you drowsy with Zopiclone. If you experience any of the above, stop the treatment with Zopiclone immediately and contact your doctor or health-care provider.

##### Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- thyroid problems;
- depression, psychosis or schizophrenia;
- epilepsy;
- addiction to drugs or medicines.

##### Tell your doctor if you plan to have surgery.

##### If you have not told your doctor or pharmacist about any of the above, tell them before you take Zopiclone GH.

##### Taking other medicines

You must tell your doctor if you are taking any other medicines including any that you buy without a prescription from a pharmacy, supermarket or health food store.

Some medicines may interfere with the absorption of zopiclone. These include:

- medicines to treat depression, anxiety and mental illness;
- St John's wort, (hypericum), a herbal remedy for depression;
- other medications which may cause drowsiness;
- benzodiazepines (medicines used as sedatives or to treat anxiety);
- pain relievers, such as opioids or narcotic analgesics;
- alcohol, (ethanol), contained in some medicines eg. cough syrups;
- muscle relaxants;
- antihistamines;
- medicines used to treat epilepsy;
- antiviral medication;
- rifampicin, erythromycin or clarithromycin (medicines used to treat infections);
- ketoconazole or itraconazole (medicines used to treat fungal infections);

These medicines may be affected by Zopiclone GH or may affect how well it works. You may need to take different amounts of your medicine or different medicines. Your doctor or pharmacist will advise you.

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

#### How to take Zopiclone GH

##### How much to take

Zopiclone should only be taken when you are able to get a full night's sleep (7 to 8 hours) before you need to be active again.

The standard adult dose of Zopiclone GH is one tablet just before you go to bed.

Zopiclone should be taken in a single intake and not readministered during the same night.

If you are over 65 years of age, the dose is half a tablet taken just before you go to bed.

If you have a liver or kidney problem, the usual recommended dose is half a tablet taken just before you go to bed.

Your doctor may have prescribed a different dose.

##### Ask your doctor if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

##### Follow the instructions they give you

If you take the wrong dose, Zopiclone GH may not work as well.

**Zopiclone GH should not be given to children or adolescents less than 18 years of age.**

##### How to take it

Swallow the tablet with a full glass of water.

### *When to take it*

Take Zopiclone GH immediately before you go to bed. Zopiclone GH should be taken as a single intake and not be readministered during the same night.

It helps put you to sleep quite quickly.

If you take Zopiclone GH on an empty stomach it may work more quickly.

**If you are not sure when to take it, ask your doctor or pharmacist.**

### *How long to take it*

Zopiclone GH should only be used for short periods (eg. 7 to 14 days). Continuous long-term use (ie. longer than 14 days) is not recommended.

**Ask your doctor or pharmacist if you are not sure how long to take the medicine for.**

### *If you forget to take it*

**If you forget to take the tablet before you go to bed, and you wake up late in the night or very early in the morning, do not take it.**

You may have trouble waking at your normal time.

### *If you take too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 in Australia or call 0800 POISON, 0800 764 766 New Zealand) for advice. Alternatively, go to the Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Zopiclone GH.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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## While you are taking Zopiclone GH

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### *Things you must do*

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Zopiclone GH.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Zopiclone GH.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.

### *Things you must not do*

**Do not take more than the recommended dose unless your doctor tells you to.**

This can increase the risk of side effects.

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

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not drink alcohol before or after taking this medicine.

This can increase the risk of side effects.

### *Things to be careful of*

**Because Zopiclone GH will make you sleepy, you should not operate dangerous machinery or drive motor vehicles for 12 hours after you take it. You should also be careful the next morning when you wake up.**

Make sure you know how you react to Zopiclone GH before you drive a car or operate machinery. This is very important if

you are taking other drugs that also make you drowsy.

Impairment can occur despite feeling fully awake, in the absence of symptoms or if you are feeling better.

**Be careful if you are over 65 and unwell or taking other medicines.**

You may be more sensitive to some of the side effects of Zopiclone GH.

**You should not drink alcohol while you are taking this medicine.**

The effects of alcohol could be made worse while taking Zopiclone GH.

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## Side effects

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All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you

**Do not be alarmed by the following lists of side effects.**

You may not experience any of them.

**Tell your doctor as soon as possible if you do not feel well while you are taking Zopiclone GH.**

It helps most people with insomnia, but it may have unwanted side effects in some people.

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

- headaches;
- dry mouth;
- bitter taste in your mouth;
- drowsiness.

These are the most common side effects of this medicine.

Less common side effects include:

- heartburn;
- nausea, vomiting and/or diarrhoea;
- change in appetite;
- stomach pain;
- rash;
- agitation;
- depression;
- confusion;
- anxiety;
- dizziness;
- blurred vision;
- impotence;
- sleep walking or other unusual behaviours (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake, some of which have been associated with serious injuries and death.
- delirium (a sudden and severe change in mental state that can cause a combination of confusion, disorientation and/or attention deficit)

Alcohol can increase the risk of sleep walking or other behaviours such as driving or eating food whilst asleep. This risk is also increased if you take more than the recommended dose.

Some sleep medicines may cause a short-term memory loss. When this occurs, a person may not remember what has happened for several hours after taking the medicine. This is usually not a problem since

most people fall asleep after taking the medicine.

Sleep medicines should in most cases, be used only for short periods of time. If your sleep problems continue, consult your doctor.

Some medicines can cause dependence, especially when they are used regularly for longer than a few weeks. People who have been dependent on alcohol or other drugs in the past may have a higher chance of becoming addicted to sleep medicines. If you have been addicted to alcohol or drugs in the past, it is important to tell your doctor before starting Zopiclone GH.

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

- **swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;**
- **hives;**
- **fainting.**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Zopiclone. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you feel you are becoming depressed, having suicidal thoughts or are experiencing changes in your behaviour.

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

Other side effects not listed above may occur in some consumers.

### *Allergic reactions*

**If you think you are having an allergic reaction to zopiclone, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing;
- swelling of the face, lips, tongue, throat or other parts of the body;
- rash, itching or hives on the skin;
- fainting;
- hayfever-like symptoms.
- suicidal thoughts or are experiencing changes in your behaviour

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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

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## After taking Zopiclone GH

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Sometimes when medicines are stopped suddenly, after being used for a long time, withdrawal symptoms may occur. Symptoms of withdrawal may include, abdominal and muscle cramps, vomiting and sweating.

In some cases your insomnia may appear worse for a short time; speak to your doctor if this occurs.

**Tell your doctor if you have any problems when you stop taking Zopiclone GH.**

**If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.**

### ***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. Protect from light.**

**Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill.**

**Do not leave it 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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## **Product description**

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

Zopiclone GH tablets are white to off white, oval, film-coated tablets with a breakline on one side and plain on the other side.

Zopiclone GH comes in blister packs of 14 tablets.

### ***Ingredients***

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

Each tablet contains 7.5 mg of zopiclone as the active ingredient.

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

- calcium hydrogen phosphate dihydrate;
- lactose monohydrate;
- sodium starch glycollate type A;
- povidone;
- maize starch;
- colloidal anhydrous silica;
- magnesium stearate;
- hypromellose;
- macrogol 6000;
- titanium dioxide;
- purified talc.

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

### ***Australian Registration Numbers***

Zopiclone GH: AUST R 239214.

### ***Sponsor***

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