

# APO-Zolpidem

Contains the active ingredient zolpidem tartrate

## Consumer Medicine Information

**WARNING: ZOLPIDEM MAY BE ASSOCIATED WITH UNUSUAL AND POTENTIALLY DANGEROUS BEHAVIOURS WHILST APPARENTLY ASLEEP. THESE HAVE INCLUDED SLEEP WALKING, DRIVING MOTOR VEHICLES AND OTHER BIZARRE BEHAVIOURS. SOME MEDICINES MAY INTERACT WITH ZOLPIDEM AND PARTICULAR CAUTION IS NEEDED WITH OTHER DRUGS THAT MAY ALSO ACT ON THE BRAIN; BEFORE YOU TAKE ZOLPIDEM REFER TO THE "TAKING OTHER MEDICINES" SECTION BELOW OR ASK YOUR DOCTOR OR PHARMACIST. YOU MUST NOT DRINK ALCOHOL WHEN YOU TAKE ZOLPIDEM. DO NOT TAKE ZOLPIDEM FOR MORE THAN 4 WEEKS. IF YOUR SLEEP PROBLEMS CONTINUE, CONSULT YOUR DOCTOR.**

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

### What is in this leaflet

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

This leaflet answers some common questions about zolpidem. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

**Ask your doctor or pharmacist:**

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

### What this medicine is used for

The name of your medicine is APO-Zolpidem. It contains the active ingredient, zolpidem tartrate.

It is used to treat people with sleeping difficulties (insomnia). It must not be used for more than 4 weeks at a time.

Zolpidem works by binding to special sites in the brain which produce sleep.

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

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

### Use in children

Children or adolescents under the age of 18 must not take this medicine.

### Before you take this medicine

**When you must not take it**

**Do not take this medicine if:**

- **You are hypersensitive to, or have had an allergic reaction to, zolpidem or any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction may include: 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; or hay fever-like symptoms.  
**If you think you are having an allergic reaction, do not take any more of the**

**medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- **You are, or have been, drinking alcohol or you believe that you may have alcohol in your bloodstream.**
- **You suffer from sleep apnoea (a condition where you temporarily stop breathing while you sleep).**
- **You suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily).**
- **You have severe liver problems.**
- **You have sudden and/or severe lung problems.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

### Before you start to take it

**Tell your doctor if:**

1. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
  - problems with your heart, liver, kidneys or lungs
  - problems breathing
  - epilepsy
  - depression
  - schizophrenia or other mental illness
  - snoring often whilst sleeping
  - addiction to alcohol, or drugs or medicines.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved. The safety of taking zolpidem during pregnancy has not been established.
4. You are currently breast-feeding or you plan to breast-feed. The use of zolpidem whilst breast-feeding is not recommended as it passes into breast milk.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with zolpidem. These include:

- medicines to treat depression, anxiety and mental illness
- strong pain relievers
- muscle relaxants

- antihistamines
- barbiturates (for sedation or epilepsy)
- anaesthetics
- any other medicines which may make you sleepy
- rifampicin, ciprofloxacin or fluvoxamine, medicines to treat infections
- ketoconazole, a medicine to treat antifungal infections.

These medicines may be affected by zolpidem 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 or pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking zolpidem.

Other interactions not listed above may also occur.

### 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 any written instructions, 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. The usual adult dose of zolpidem is 10 mg.

If you are over 65 years of age or debilitated in any way, the usual dose is 5 mg at night.

If you have a liver problem, the usual dose is 5 mg. This can be increased to 10 mg if advised by your doctor.

### How to take it

Swallow the tablets whole with a full glass of water unless your doctor has told you to take half a tablet.

**Do not crush or chew the tablets.**

### When to take it

Take zolpidem immediately before you go to bed because it puts you to sleep quite quickly. It also works more quickly if you take it on an empty stomach.

Zolpidem 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 and alert again.

### How long to take it for

Zolpidem should only be used for short periods (treatment should not exceed 4 weeks).

Continuous long term use is not recommended unless advised by your doctor.

*If you forget to take it*

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

If you take it later than normal, you may have trouble waking at your normal time.

**Do not take a double dose to make up for missed doses.**

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

*If you take too much (overdose)*

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.**

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

If you take too much zolpidem your consciousness may be impaired (ranging from drowsiness to light coma), or can be fatal.

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### While you are taking this medicine

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#### *Things you must do*

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant. If you become pregnant while you are taking zolpidem, stop taking it and tell your doctor immediately
- you are breastfeeding or are planning to breastfeed. Breast-feeding is not recommended whilst taking zolpidem
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

**If the tablets have not started to work after 7 to 14 days go to your doctor to discuss what to do next.**

**Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.**

#### *Things you must not do*

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

**Do not take your medicine to treat any other condition unless your doctor tells you to.**

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

If you stop taking this medicine suddenly, there is a chance that your original symptoms of sleeplessness may become worse, or you get withdrawal symptoms such as muscle pain, sensitivity to light, touch or sound, headache, anxiety, tension, restlessness, confusion, strange thoughts, numbness, tingling, mood changes, irritability or, feeling not part of your body.

**Do not drink alcohol before, during or immediately after taking this medicine. This can increase the risk of side effects.**

#### *Things to be careful of*

**Because zolpidem will make you sleepy or effect your alertness and response time, you**

**should not operate dangerous machinery or drive motor vehicles for at least 8 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 zolpidem before you drive a car or operate machinery. This is especially important if you are taking other drugs that also make you drowsy, because they may make you even drowsier when taken with zolpidem.

**Be careful if you are over the age of 65, unwell or debilitated in some way, or taking other medicines. You may be more sensitive to some of the side effects of zolpidem.**

**You must not have alcohol in your bloodstream while you are taking zolpidem. The effects of alcohol could be made worse while taking zolpidem.**

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### Possible side effects

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- drowsiness
- dizziness
- headache
- fatigue
- worsened insomnia
- nightmares
- hallucinations
- agitation
- temporary amnesia
- diarrhoea, nausea and vomiting
- abdominal pain
- muscle weakness
- sensation of pins and needles, or numbness
- infections of the nose throat and chest
- blurred vision
- change in appetite.

Tell your doctor as soon as possible if you notice any of the following. These may be serious side effects and you may need medical attention:

- **unexpected changes in behaviour, such as anger, aggression or rage, worsened insomnia, nightmares, confusion, agitation, restlessness, irritability, stimulation, excitement, hallucinations, delusions, suicidal thoughts or attempts, and other forms of unwanted behaviour**
- **sleep walking, driving motor vehicles and other unusual, and on some occasions, dangerous behaviours whilst apparently asleep. These have also included preparing and eating food, making phone calls or having sexual intercourse. People experiencing these effects have had no memory of the events. Alcohol can increase the risk of having these strange experiences. These side effects can also occur without the presence of alcohol intake. They can also occur at the dosage prescribed by your doctor. However, there is an increased risk of side effects if you take more than the recommended dose.**

Some sleep medicines may cause 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.

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

#### **Dependence**

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

Some sleep 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 zolpidem.

#### **Withdrawal Symptoms**

Sometimes when medicines are stopped suddenly, after being used for a long time, withdrawal symptoms may occur. Symptoms of withdrawal may include muscle pain, sensitivity to light, touch or sound, headache, anxiety, tension, restlessness, confusion, strange thoughts, numbness, tingling, mood changes, irritability or feeling not part of your body.

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

Patients taking part in trials have not had any problems when they stopped taking zolpidem.

**However, let your doctor know if you have any problems when you stop taking zolpidem.**

#### *Allergic reactions*

**If you think you are having an allergic reaction to zolpidem, 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
- hay fever-like symptoms.

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### Storage and disposal

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#### *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 30°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 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 APO-Zolpidem looks like*

#### **5 mg tablets:**

Pink, capsule-shaped, film-coated tablets, imprinted "APO" on one side and "ZOL 5" on the other side.

Packs of 7 and 14 tablets.

#### **10 mg tablets:**

White, modified oval, scored tablets, imprinted "APO" on one side and "1" European bisect "0" on the other side.

Packs of 7 and 14 tablets.

\* Not all strengths, pack types and/or pack sizes may be available.

### *Ingredients*

Each tablet contains 5 or 10 mg of the active ingredient, zolpidem tartrate.

It also contains the following inactive ingredients:

- microcrystalline cellulose
- sodium starch glycollate
- magnesium stearate
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- iron oxide red (CI77491) (5 mg only).

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

### *Australian Registration Numbers*

APO-Zolpidem 5 mg tablets (blister): AUST R 127151.

APO-Zolpidem 5 mg tablets (bottle): AUST R 127167.

APO-Zolpidem 10 mg tablets (blister): AUST R 127174.

APO-Zolpidem 10 mg tablets (bottle): AUST R 127178.

### *Sponsor*

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