

ZOLPIBELL

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.

What is in this leaflet?

This leaflet answers common questions about ZOLPIBELL. 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 risk of taking ZOLPIBELL against the benefits it is expected to 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 want to read it again.

What ZOLPIBELL is used for?

ZOLPIBELL is a prescription medicine that your doctor has prescribed for you. Do not share it with anyone. ZOLPIBELL is the brand name of a medicine called Zolpidem tartrate.

What is it used for and how does it work?

ZOLPIBELL is used to initiate and maintain sleep in those with sleeping difficulties, also called insomnia. The cause of sleeping problem should be known, if possible. The causes should be treated before ZOLPIBELL, or any hypnotic is prescribed. It should not be used for more than 4 weeks at a time. Continuous long term use is not recommended unless

advised by your doctor. The use of ZOLPIBELL may lead to dependence on the medicine.

ZOLPIBELL has a different chemical structure to any other sleeping tablet that is currently available in Australia. ZOLPIBELL works by binding to special sites in the brain which produce sleep. Your doctor, however may prescribe Zolpidem for another purpose. Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

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

BEFORE YOU TAKE ZOLPIBELL

When you must not take ZOLPIBELL

Do not take ZOLPIBELL if you have:

- 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

Do not take ZOLPIBELL 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 ZOLPIBELL to a child or an adolescent.

There is no experience with its use in children or adolescents under 18 years old.

Do not take it 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 to taking it if you are pregnant.

Do not take it if you are breast-feeding or planning to breast-feed.

ZOLPIBELL 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 breast-feeding or planning to breast-feed.

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

Before you start to take ZOLPIBELL

Tell your doctor if you have allergies any of the ingredients listed at the end of this leaflet.

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

Like most medicines of this kind, ZOLPIBELL 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 breast-feeding or planning to breast-feed.

ZOLPIBELL can pass into breast milk. Your doctor will discuss the risks and benefits of using it if you are breast-feeding or planning to breast-feed.

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 ZOLPIBELL.

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

- **Problems with your liver, kidney or lungs**
- **Epilepsy**
- **Depression**
- **Schizophrenia**

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you take ZOLPIBELL.

Taking other medicines

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

Some medicines may interfere with ZOLPIBELL. These include:

- Medicines to treat depression, anxiety and mental illness
- Pain relievers
- Muscle relaxants

- antihistamines
- rifampicin – a medicines to treat infections
- Medicines to treat fungal infections such as ketoconazole. (Patients should be advised that use of Zolpibell with ketoconazole may enhance the sedative effects of Zolpibell)
- The use of alcohol and other CNS depressants with Zolpibell appears to increase the risk of sleep walking (somnambulism) and associated behaviours

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

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

HOW TO TAKE ZOLPIBELL

How much to take

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

The usual adult dose of ZOLPIBELL is 10 mg . If you are over 65 years of age, debilitated or have liver problems you may be particularly sensitive to the effects of zolpidem tartrate, therefore 5mg* dose is recommended.

(*Please note as Zolpibell is only available in a 10mg strength tablet, an alternative brand of zolpidem which can provide a 5mg strength should be used)

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, ZOLPIBELL may not work as well. If you take too much your consciousness may be impaired (see 'Overdose below').

ZOLPIBELL should not be given to children or adolescents less than 18 years of age.

How to take it

Swallow the tablets whole with a full glass of water or other liquid.

When to take it

Take ZOLPIBELL immediately before you go to bed.

It helps you to sleep quite quickly. If you take ZOLPIBELL 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

Usually, ZOLPIBELL or any other medicines to treat sleeping disorders should only be used for short periods (eg. 2 to 14 weeks). Continuous long term use is not recommended unless advised by your doctor.

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

If you forget to take your dose

If you forget to take ZOLPIBELL before you go to bed and you wake up late in the night or early morning, do not take any ZOLPIBELL as you may have trouble waking at your normal time.

If you are not sure what to do, ask your doctor.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much ZOLPIBELL.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much ZOLPIBELL, your consciousness may be impaired, ranging from drowsiness to light coma.

WHILE YOU ARE USING ZOLPIBELL

Things you must do

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking ZOLPIBELL.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ZOLPIBELL.
- 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 this medicine with alcohol
- Do not take more than the recommended dose unless your doctor tells you to.
- Do not give medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

Things to be careful of

Because ZOLPIBELL will make you sleepy, you should not operate dangerous machinery or drive motor vehicles after you take it. You should also be careful the next morning when you wake up. Make sure you know how you react to ZOLPIBELL before you drive a car or operate machinery. This is very important if you are taking other drugs that make you drowsy.

Be careful if you are elderly, unwell or taking other medicines.

You may be more sensitive to some of the side effects such as drowsiness, confusion, dizziness and

unsteadiness, which may increase the risk of a fall.

Reports warn of the possibility of sleep walking and other associated behaviours such as “sleep driving”, preparing and eating food, and making phone calls while taking ZOLPIBELL. It is recommended that ZOLPIBELL be discontinued if any of these events occurs.

The effects of alcohol could be made worse while taking ZOLPIBELL.

Your doctor may suggest that you avoid alcohol while you are taking ZOLPIBELL.

SIDE EFFECTS

All medicines can have unwanted effects. Sometimes they are serious, 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 this list of possible side effects. You may not experience any of them.

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

- Drowsiness,
- Dizziness
- Headache
- Nausea
- Vomiting
- Diarrhoea
- Muscle weakness

These are the more common side effects of ZOLPIBELL.

Less common adverse effects include:

- Unexpected changes in behaviour. These have included rage reactions, worsened insomnia, confusion, agitation, hallucinations 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.

The fact that such side effects can occur without alcohol intake and that alcohol intake heightens the risk of such side effects.

That these side effects can occur at therapeutic doses.

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 not usually 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 ZOLPIBELL.

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

- **Fainting**
- Skin rashes or hives, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- Aggressiveness, unusual changes in behaviour or mood agitation, hallucinations.

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

All of these side effects are very rare.

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.

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.

AFTER TAKING IT

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.

Patients taking part in trials have not had any problems when they stopped taking this product. However let your doctor know if you have any problems when you stop taking ZOLPIBELL

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

IF YOU TAKE TOO MUCH

Some signs and symptoms of taking too much ZOLPIBELL include severe drowsiness, clumsiness or unsteadiness, mental or mood changes, unusual tiredness or weakness and unconsciousness.

If you or someone else has taken too much ZOLPIBELL, immediately telephone your doctor or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

HOW TO STORE ZOLPIBELL PROPERLY

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the box or the blister pack they may not keep well
- Store below 25°C
- Do not store Zolpibell or any other medicine in the bathroom, near a sink, or in a windowsill.
- Do not leave it in the car. Heat and damp can destroy some medicines.
- Keep ZOLPIBELL in a dry place
- Keep it where children cannot reach it. A locked cupboard at least one and a half metres above ground is a good place to store medicines.

Disposal:

If your doctor tells you to stop taking, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused or out of date medicine to your pharmacist

Who do I ask if I have any questions about ZOLPIBELL?

This leaflet does not tell you all that is known about ZOLPIBELL. Please take any questions or problems that you may have about ZOLPIBELL to your doctor or pharmacist. They will be happy to discuss them with you.

What is in ZOLPIBELL?

Each ZOLPIBELL tablet contains zolpidem tartrate as the active ingredient plus:

lactose
microcrystalline cellulose
hypromellose
sodium starch glycollate
magnesium stearate

The coating contains hypromellose, titanium dioxide (E171) and Macrogol 400.

ZOLPIBELL 10mg AUST R 119087 (blister pack) are available in:

1 blister pack of 14 tablets

Who distributes ZOLPIBELL?

Generic Health Pty Ltd
Suite 1, Level 1
1175 Toorak Road
CAMBERWELL VIC 3126

Date of preparation: 8 December 2006

Date of Approval: 19 January 2007

Date of last amendment: December 2012