

ZOLPIDEM PHARMACOR

Zolpidem tartrate

Consumer Medicine Information

Warning: Zolpidem may be associated with unusual and potentially dangerous behavior whilst apparently asleep. These have included sleep walking, driving motor vehicles and other bizarre behaviors. 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 some common questions about ZOLPIDEM PHARMACOR.

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 ZOLPIDEM PHARMACOR 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 ZOLPIDEM PHARMACOR is used for

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

ZOLPIDEM PHARMACOR is used to initiate sleep in those with sleeping difficulties, also called insomnia. The cause of the sleeping problem should be known, if possible. The causes should be treated before ZOLPIDEM PHARMACOR, or any hypnotic is

prescribed. It is not recommended for use for more than 4 weeks at a time.

Continuous long term use is not recommended unless advised by your doctor. The use of ZOLPIDEM PHARMACOR may lead to dependency on the medicine.

ZOLPIDEM PHARMACOR has a different chemical structure to other sleeping tablets. ZOLPIDEM PHARMACOR works by binding to special sites in the brain which produce sleep.

Your doctor, however, may prescribe ZOLPIDEM PHARMACOR 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 ZOLPIDEM PHARMACOR

When you must not take it

Do not take ZOLPIDEM PHARMACOR 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.

Do not take ZOLPIDEM PHARMACOR 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 ZOLPIDEM PHARMACOR to a child or 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 of taking it if you are pregnant.

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

ZOLPIDEM PHARMACOR 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 it

Tell your doctor if you have allergies to 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, ZOLPIDEM PHARMACOR 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. ZOLPIDEM PHARMACOR 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 ZOLPIDEM PHARMACOR.

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

- problems with your liver, kidneys 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 ZOLPIDEM PHARMACOR.

Taking other medicines

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

Some medicines may interfere with ZOLPIDEM PHARMACOR. These include:

- medicines to treat depression, anxiety, and mental illness
- medicines to treat epilepsy
- pain relievers
- muscle relaxants
- antihistamines
- Rifampicin, a medicine to treat infections
- Ketoconazole, a medicine to treat antifungal infections. (Patients should be advised that the use of ZOLPIDEM PHARMACOR with Ketoconazole may enhance the sedative effects of ZOLPIDEM PHARMACOR.)
- The use of alcohol and other CNS depressants with ZOLPIDEM PHARMACOR appears to increase the risk of sleep walking (somnambulism) and associated behaviors.

These medicines may be affected by ZOLPIDEM PHARMACOR, or may affect how well it works. You may need to use different amounts of your medicine, or 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 ZOLPIDEM PHARMACOR.

How to take ZOLPIDEM PHARMACOR

How much to take

ZOLPIDEM PHARMACOR 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 usual adult dose of ZOLPIDEM PHARMACOR 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, 5 mg* dose is recommended.

(* Please note as ZOLPIDEM PHARMACOR is only available in a 10 mg strength tablet, an alternative brand of ZOLPIDEM PHARMACOR which can provide a 5 mg 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, ZOLPIDEM PHARMACOR may not work as well. If you take too much your consciousness may be impaired (see 'Overdose' below).

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

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take ZOLPIDEM PHARMACOR immediately before you go to bed.

It helps put you to sleep quite quickly. If you take ZOLPIDEM PHARMACOR 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, ZOLPIDEM PHARMACOR or any other medicines to treat sleeping disorders should only be used for short periods (eg 2 to 4 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 it

If you forget to take ZOLPIDEM PHARMACOR before you go to bed, and you wake up late night or early morning, do not take any ZOLPIDEM PHARMACOR 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 Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ZOLPIDEM PHARMACOR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking ZOLPIDEM PHARMACOR

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ZOLPIDEM PHARMACOR.

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

If you plan to have surgery that needs a general anesthetic, 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 this 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 ZOLPIDEM PHARMACOR 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 ZOLPIDEM PHARMACOR before you drive a car or operate machinery. This is very important if you are taking other drugs that also make you drowsy.

Be careful if you are over 65, 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 behaviors such as “sleep driving”, preparing and eating food, and making phone calls while taking ZOLPIDEM PHARMACOR.

It is recommended that ZOLPIDEM PHARMACOR be discontinued if any of these events occur.

The effects of alcohol could be made worse while taking ZOLPIDEM PHARMACOR.

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

Side effects

All medicines can have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them. Your doctor or pharmacist has weighed the risks of using this

medicine against the benefits they expect it will have for you.

Tell your doctor as soon as possible if you do not feel well while taking ZOLPIDEM PHARMACOR.

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:

- drowsiness
- dizziness
- headache
- nausea
- vomiting
- diarrhoea
- muscle weakness.

These are the more common side effects of ZOLPIDEM PHARMACOR. Mostly, these are mild and short-lived.

Less common adverse effects include:

- Unexpected changes in behavior, including rage reactions, worsened insomnia, confusion, agitation, hallucinations and other forms of unwanted behavior
- 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.

These side effects can occur at therapeutic doses and without alcohol intake. Alcohol can increase the risk of such side effects.

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.

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 ZOLPIDEM PHARMACOR.

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:

- **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 behavior or mood agitation, and hallucinations.**

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

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.

If you take too much

Some signs and symptoms of taking too much ZOLPIDEM PHARMACOR 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 ZOLPIDEM PHARMACOR, immediately telephone your doctor or Poisons Information Centre (telephone 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.

After taking ZOLPIDEM PHARMACOR

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 ZOLPIDEM PHARMACOR.

However, let your doctor know if you have any problems when you stop taking ZOLPIDEM PHARMACOR.

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 tablets in the blister pack until it is time to take them.

If you take the tablets out of the box or blister pack they may not keep well.

Keep ZOLPIDEM PHARMACOR in a cool, dry place where the temperature stays below 25°C.

Do not store ZOLPIDEM PHARMACOR or any other

medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the medicine or it 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.

Product description

What it looks like

ZOLPIDEM PHARMACOR 10 mg is a white, oval, bi-convex, film coated tablets, scored on both sides and embossed with "ZIM 10" on one side.

ZOLPIDEM PHARMACOR 10 mg tablets are available in boxes of 7, 10, and 14 tablets*.

* Not all pack size may be marketed.

Ingredients per tablet

Active ingredient:
10 mg Zolpidem tartrate

Inactive ingredients:

- Lactose monohydrate
- Cellulose - microcrystalline
- Hypromellose
- Magnesium stearate
- Sodium starch glycolate
- Opadry white complete film coating system Y-1-7000 (PI 2058).

Manufacturer/Sponsor

ZOLPIDEM PHARMACOR is supplied in Australia by:

PHARMACOR Pty. Ltd.
Suite 501, 7 Oaks Avenue
Dee Why NSW 2099
Australia

This leaflet was prepared in August
2016.

Australian Register Number(s):
ZOLPIDEM PHARMACOR
Zolpidem tartrate 10 mg tablet blister
pack - **AUST R 131918**.