

APO-ZOPICLONE

Zopiclone

Consumer Medicine Information

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

What is in this leaflet

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 using 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 the medicine.

You may want to read it again.

What this medicine is used for

Zopiclone is used to help people with sleeping difficulties (insomnia). It helps you fall asleep and reduces the number of times you wake up during the night. It is used for short term treatment (2-4 weeks) of insomnia. It is not recommended for use for more than 4 weeks at a time.

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.

This medicine should not be used in children. The safe and effective dose of this medicine in children and adolescents under 18 years of age has not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- zopiclone
- any of the ingredients listed at the end of this leaflet.

Some of the 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
- hay fever-like symptoms.

Do not take this medicine if you have or have had any of the following medical conditions:

- sleep apnoea
- myasthenia gravis
- severe liver problems
- severe lung problems.
- stroke

Do not take this medicine if you recently had alcohol or believe that you may have alcohol in your bloodstream.

Do not take this medicine 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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- thyroid problems
- depression, psychosis or schizophrenia or are taking medication for a mental illness
- epilepsy
- kidney or liver problems
- lung problems or breathing problems
- disability
- alcoholism or frequently consume alcohol
- have been addicted to any drug or medicine

Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding.

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor if 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 zopiclone.

These include:

- medicines to treat depression, anxiety and mental illness (e.g. antipsychotics)
- other sedatives or tranquillisers
- strong pain relievers (e.g. codeine)
- muscle relaxants
- antihistamines
- antiepileptics (e.g. phenytoin, carbamazepine, phenobarbital)
- certain medicines used to treat infections (e.g. rifampicin, clarithromycin, erythromycin, ketoconazole, itraconazole, ritonavir)
- St John's Wort.

If you are taking any of these, you may need a different dose, or you may need to take different medicines. Other medicines not listed above may also interact with zopiclone.

How to take this medicine

Follow carefully all directions given to you by your doctor.

They may differ to the information contained in this leaflet.

Your doctor may have prescribed a different dose, depending on your condition and if you are taking any other medicines.

How much to take

The usual dose is one tablet just before you go to bed.

Elderly people and people with liver problems may need smaller doses.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

This medicine should be taken when you are able to have a full night sleep and immediately before you go to bed. It helps put you to sleep quite quickly.

If you take this medicine on an empty stomach it may work more quickly.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

This medicine should only be used for short periods (2 to 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 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.

Take the next dose the following night when you are meant to.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to the Emergency department at your nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

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

If you become pregnant whilst taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, surgery, anaesthetic or are going into hospital, tell your doctor.

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

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 take for a longer time than the doctor has prescribed.

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

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

Do not drink alcohol before, with or after this medicine.

Things to be careful of

This medicine will cause drowsiness. You should not operate dangerous machinery or drive motors for 12 hours after you take it. You should be careful the next morning when you wake up.

Make sure you know how you react to this medicine 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 and unwell or taking other medicines.

You may be more sensitive to some of the side effects of this medicine.

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

The effects of alcohol could be made worse while taking this medicine.

If you have been addicted to alcohol or drugs in the past, it is important to tell your doctor before starting this medicine.

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.

Side effects

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

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor if you notice any of the following:

- headaches
- dry mouth, bitter taste in your mouth
- drowsiness, fatigue

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:

- heartburn
- nausea, vomiting and/or diarrhoea
- change in appetite
- stomach pain
- rash
- agitation
- breathing difficulties
- depression, anxiety
- confusion
- dizziness
- blurred vision
- impotence
- sleep walking or other behaviours whilst asleep

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.

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

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 Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all 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.

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 insomnia, confusion, headache, muscle cramps and sweating.

Tell your doctor if you have any problems when you stop taking this medicine.

Storage and disposal

Storage

Keep your medicine in its pack until it is time to take it.

If you take your medicine out of its pack 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 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 the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product description

What it looks like

White to off white oval film coated tablets with breakline on one side and plain on the other side.

Blister packs of 30 tablets. AUST R 213071.

Ingredients

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

It also contains the following inactive 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 does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trademarks of Apotex Inc.

This leaflet was prepared in June 2019.