

## APO- ZOPICLONE

Contains the active ingredient zopiclone

### Consumer Medicine Information

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 zopiclone. 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- Zopiclone Tablet. It contains the active ingredient zopiclone.

It is used to help people 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 (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.

##### Use in children

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 or have had any of the following:**
  - 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
  - severe lung problems.
- **You recently had alcohol or believe that you may have alcohol in your bloodstream.**
- **You have had a stroke.**
- **You are hypersensitive to, or have had an allergic reaction to, zopiclone 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.**

- **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.

##### Do not give this medicine to children or adolescents under 18 years of age

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

##### Before you start to take it

##### Before you start taking this medicine, 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:
  - thyroid problems
  - depression, psychosis or schizophrenia
  - epilepsy
  - kidney problems
  - liver problems
  - lung problems or breathing problems.
3. You have a disability.
4. You are or have been addicted to alcohol or any drug or medicine.
5. You frequently consume alcohol.
6. You are taking medication for a mental illness.
7. 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.
8. You are currently breastfeeding or you plan to breast-feed.

Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
9. You are planning to have surgery or an anaesthetic.
10. You are currently receiving or are planning to receive dental treatment.
11. 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
- other sedatives or tranquillisers
- strong pain relievers, such as codeine
- muscle relaxants

- antihistamines
- antipsychotics
- antiepileptics such as carbamazepine, phenobarbital and phenytoin
- certain antibiotics such as rifampicin, clarithromycin and erythromycin
- ketoconazole and itraconazole, medicines to treat fungal infections
- ritonavir, used to treat HIV
- 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. Their instructions may be different to the information in this leaflet.

##### 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.

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

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

Your doctor may have prescribed a different dose. This depends on your condition and whether or not you are taking any other medicines.

**This medicine 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

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 (eg 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)

**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.**

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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
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

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.
- Take for a longer time than the doctor has prescribed.
- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Drink alcohol before or after taking this medicine. Do not drink alcohol with this medicine.

#### *Things to be careful of*

**This medicine will cause drowsiness. You should not operate dangerous machinery or drive motors for 8 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.

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 this medicine.

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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 zopiclone 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:**

- 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
- depression
- confusion
- anxiety
- 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 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.

#### *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.

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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 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 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- Zopiclone tablets look like*

##### **7.5mg film-coated tablets**

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

Blister packs of 30 tablets

#### *Ingredients*

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

It also contains the following inactive ingredients:

- calcium hydrogen phosphate dibasic
- 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*

APO-Zopiclone 7.5mg Tablets (Blisters): AUST R 213071.

#### *Sponsor*

Apotex Pty Ltd  
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