

APO-ZOPICLONE TABLET

Zopiclone (7.5mg)

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What Apo-Zopiclone is used for

Apo-Zopiclone may be used for short term treatment of difficulties in falling asleep, waking up at night or early in the morning or difficulty in sleeping caused by events, situations or mental illness, which is severe, disabling or causing great distress.

How Apo-Zopiclone works

Apo Zopiclone tablet contains the active ingredient zopiclone. It belongs to a group of medicines called hypnotics (sleeping pills), which works by acting on the brain to cause sleepiness.

Before you use Apo-Zopiclone

- When you must not use it

Do not take Apo-Zopiclone and tell your doctor if you:

- are allergic (hypersensitive) to Apo-Zopiclone or any of the other ingredients (see section **Product Description**) in the tablet. An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- have severe liver problems
- suffer from breathing problems whilst sleeping (sleep apnoea syndrome)
- suffer from severe muscle weakness (myasthenia gravis)

- Before you start to use it

Check with your doctor or pharmacist before taking Apo-Zopiclone if you:

- have any lung, kidney or liver problems.

- have a history of mental illness
- have or have ever had a history of or tendency to alcohol or drug abuse or personality disorders. The risk of dependence to Apo-Zopiclone tablets (physical or mental effects produced by a compulsion to keep taking the medicine) increases in these patients, and with dose and length of treatment.
- are pregnant, think you might be pregnant now, are planning to become pregnant or if you are breast-feeding. Do not take Apo-Zopiclone until you and your doctor have discussed the risks and benefits involved.

Please tell your doctor if you have any of the conditions listed above.

Other considerations

- *Habituation* – if after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should go and see your doctor as an adjustment to your dosage may be required.
- *Dependence* – when taking this type of medicine there is a risk of dependence, which increases with dose and length of treatment. There is a greater risk in patients with a history of alcohol or drug abuse or personality disorders.
- *Withdrawal* – treatment should be gradually withdrawn. A transient syndrome whereby the symptoms that led to treatment with Apo-Zopiclone tablets recur in an enhanced form, may occur on withdrawal. It may be accompanied by other reactions including mood changes, anxiety and restlessness.
- *Amnesia* – Apo-Zopiclone tablets can cause memory loss. To reduce this risk you should ensure that you are able to have a full night of uninterrupted sleep.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any

other medicine including medicines obtained without a prescription.

Apo-Zopiclone tablets may influence the effect and/or side effects of other medicines. If you see another doctor or go into hospital, particularly if you are having an operation under anaesthesia, tell the doctor which medicines you use. The following medicines may increase the sedating effect of Apo-Zopiclone tablets:

- medicines to treat mental illness (antipsychotics)
- medicines to treat depression
- other sleeping pills
- medicines to treat anxiety and other tranquillizers
- narcotics (strong pain killers) e.g. codeine, morphine
- medicines used to treat epilepsy
- anesthetics (used during surgery)
- antihistamine medicines (used for allergy or cold) which cause sleepiness
- medicines inhibiting liver enzymes e.g. cimetidine, allopurinol, propranolol. Ask your doctor or pharmacist which medicines have this effect.
- erythromycin (an antibiotic to treat infections).

How to use Apo-Zopiclone

- How much to use

Always take Apo-Zopiclone tablets exactly as your doctor has told you. You should check with your doctor or pharmacist when you are not sure. The usual dose is:

- *Adults*: 7.5mg before going to bed.
- *Elderly*: A lower dose of 3.75mg may be used initially. This dose may be increased to 7.5mg.
- *Children*: not recommended for use
- *If you have liver or lung problems*: Usually a lower dose of 3.75mg at night. Up to 7.5mg can be given.

- When to use it

The tablet should be taken together with liquid immediately before going to bed.

Use as directed by your doctor or pharmacist

- How long to use it

Continue taking Apo-Zopiclone for as long as your doctor recommends.

This medicine should only be used for short periods (usually do not exceed 7-10 consecutive days.). Continuous long term use is not recommended unless advised by your doctor.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think 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.

If you take too much of this medication, you might experience prolonged sleep, drowsiness, lethargy and/or ataxia (an impaired ability to coordinate movement).

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Zopiclone.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Apo-Zopiclone to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Complex sleep-related behaviors

There have been reports of people doing things while they are asleep after taking this medicine that they do not remember when they wake up. These include sleep walking, sleep driving, making phone calls and preparing and eating food.

Elderly may be particularly susceptible to the sedative effects of this medication, which may increase the possibility of a fall.

Side effects

Like all medicines, Apo-Zopiclone tablets can cause unwanted side effects, although not everybody gets them. If you experience the following rare, but very serious side effect, stop taking Apo-Zopiclone tablets and tell your doctor immediately or contact the casualty department at your nearest hospital:

- *an allergic reaction:* skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing or light headedness, lack of co-ordination.

Tell your doctor or pharmacist if any of the following side effects occur or worsen:

- *Effects on the gastrointestinal system:* a bitter or metallic taste in the mouth, dry mouth and feeling sick or being sick.
- *Effects on the nervous system:* headache, dizziness, drowsiness, irritability, aggressiveness, confusion, depression, amnesia, hallucinations (hearing voices or seeing things which are not there) or nightmares.
- *Other:* sometimes sleeplessness has occurred on stopping the tablets, usually following prolonged use.

If any of the side effects get worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Apo-Zopiclone

- Storage

Keep out of the reach and sight of children.

Store below 25°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Each oval, blue, film-coated biconvex tablets, scored and engraved 'APO 7.5' on one side, other side plain,

- Ingredients

- Active ingredient
Zopiclone

- Inactive ingredients
Hydroxypropyl Methylcellulose
2910 E-5 USP, Titanium Dioxide
USP, Polyethylene Glycol NF 3350,
Carnauba Wax Powder, Magnesium
stearate NF, Brilliant Blue FCF
CI42090, Lactose Monohydrate
(Spray Dried), D&C Yellow No. 10
(CI 47005),
MICROCRYSTALLINE
CELLULOSE PH102.

- MAL number:

MAL19986964AR

Manufacturer

Apotex Inc.
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Product Registration Holder

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