

ZOPIM F.C. TABLETS 10MG “S.T”

Zolpidem hemitartrate (10mg)

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What Zopim Tablet is used for

Zopim Tablet is used for the treatment of insomnia.

How Zopim Tablet works

The active ingredient in this medicine is Zolpidem hemitartrate. Zopim Tablet belongs to a group of medicines called hypnotics. It works by acting on your brain chemicals to help you sleep.

Before you use Metoclopramide Tablet

- When you must not use it

Do not use Zopim Tablet if you:

- are allergic to Zolpidem hemitartrate or any other ingredients in the product (see section **Product description**).
- have obstructive sleep apnoea (stop breathing for short periods at night)
- have muscle weakness
- severe liver problem
- acute and/or severe respiratory depression

Do not use in children or people with psychotic illness.

- Before you start to use it

You should check with your doctor if you have

- If you have kidney disease
- If you have liver disease
- If you plan or are undergoing surgery
- If you have depression or have had another mental illnesses in the past
- If you have a history of alcohol or drug abuse

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, planning to become pregnant, or breast-feeding. The use of Zopim Tablet in pregnancy and nursing mothers is not recommended. Do not take Zopim Tablet until you and your doctor have discussed the risks and benefits involved.

- Taking other medicines

There are a few medicines which may interact with Zopim Tablet. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to your doctor or pharmacist if you are taking:-

- Other medicines to calm or reduce anxiety, including benzodiazepines
- Medicines to treat depression and other mental illness
- Medicines to treat infections, such as rifampin

Other medicines not listed above may also interact with Zopim Tablet. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Zopim Tablet

- How much to use

You should take Zopim Tablet exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

The usual recommended dose for adults is 10mg. Normal daily dose and maximum dosage should never exceed 10 mg per day.

Elderly/Liver problems

If you are elderly, or you are having liver problems, a lowered dose should be given, and may be gradually increased if needed and as tolerated.

- When to use it

Use Zopim Tablet as directed by your doctor or pharmacist.

- How long to use it

It is important to take Zopim Tablet as long as your doctor prescribes. Usually, Zopim Tablet or any other medicines to treat sleeping disorders should only be used for short periods (from a few days to 4 weeks). Continuous long term use is not recommended unless advised by your doctor. Zopim Tablet should always be taken just before going to bed.

- If you forget to use it

Zopim Tablet should be only taken at bedtime. 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 feel drowsy and confused during the day.

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.

Taking too much tablet may cause your consciousness to be impaired, ranging from drowsiness to light coma.

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

- Things you must not do

Do not stop taking Zopim Tablet or lower the dose without first checking with your doctor. Your doctor will tell you how to slowly reduce your dose of Zopim Tablet before you can stop taking it completely.

Stopping this medicine suddenly may cause some unwanted effects, such as headache, muscle pain, extreme anxiety, confusion and restlessness. Severe unwanted effects may include depersonalisation (feelings of unreality and strangeness concerning oneself or the environment) and hallucinations (hearing voices or seeing things which are not there).

- 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.

Concomitant use with alcohol

Combining Zopim Tablet and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking this medicine.

Complex sleep-related behaviours

Sleep-driving and other strange behaviours such as making phone calls, preparing and eating food (while asleep) may occur.

Amnesia

You could experience amnesia (total or partial memory loss) when taking this medicine.

Tolerance

If after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should speak to your doctor.

Dependence

When taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse. Therefore, you should take Zopim Tablet for a short a period of time as possible.

Side effects

Like all medicines, Zopim Tablet can cause side effects, although not everybody gets them.

The possible side effects are daytime drowsiness, reduced alertness, confusion, fatigue, headache, dizziness, muscle weakness, gait disturbances or diplopia (seeing doubles). Other like gastrointestinal disturbances, changes in libido (sexual desires) or skin reactions have been reported occasionally.

For psychiatric and paradoxical reactions, contact your doctor if you experience reactions like restlessness, agitation, irritability, aggressiveness, delusion (firmly held false beliefs), nightmares, hallucinations (hearing voices or seeing things which are not there), and other adverse behavioural effects. Such reactions are more likely to occur in the elderly.

Any other effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other symptoms while taking this medication.

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

Storage and disposal of Zopim Tablet***- Storage***

Store at or below temperature 30 °C. Protect from heat and moisture.

- 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***

White, oblong, biconvex tablet, a S/T is scored on the one side and 385 on the other side.

- Ingredient(s)***- Active Ingredient***

Zolpidem hemitartrate

- Inactive Ingredients

- Hydroxypropyl Cellulose
- Magnesium Stearate
- Food Color Red No. 6 (ponceau 4R)
- Corn Starch
- Alcohol 95%
- Avicel 101
- Sodium Starch Glycolate
- Povidone
- Titanium Dioxide

- MAL number

MAL06091401A

Manufacturer

Taiwan Biotech Co., Ltd.
22, Chieh-Shou Road, Taoyuan, Taiwan,
R.O.C.

Product Registration Holder

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