

TORZOLP TABLETS

Zolpidem Tartrate (10mg)

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What Torzolp is used for

Torzolp is used for temporary sleep problems that are causing you severe distress or that are affecting your everyday life. This includes sleep problems such as:

- Difficulty falling asleep.
- Waking in the middle of the night.
- Waking too early.

How Torzolp works

Torzolp contains a medicine called zolpidem tartrate. This belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

Before you use Torzolp

- When you must not use it

Do not take Torzolp:

- If you are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients of Torzolp.
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Torzolp.

Pregnancy and lactation

Do not take Torzolp if you are pregnant or plan to become pregnant or think you might be pregnant.

Do not take Torzolp if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Check with your doctor or pharmacist before taking your medicine if:

- You have a history of alcohol or drug abuse.
- You have liver problems.
- You have depression or have had another mental illnesses in the past.
- You have recently taken Torzolp or other similar medicines for more than four weeks.
- You are elderly.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Torzolp.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

This includes medicines you buy without a prescription, including herbal medicines. This is because Torzolp can affect the way some other medicines work. Also some medicines can affect the way Torzolp works.

Tell your doctor if you are taking any of the following medicines:

Torzolp may increase the effect of the following medicines:

- Any drug with CNS-depressant effects could potentially enhance the CNS-depressant effects of zolpidem. Thus such medicines should be avoided.
- Drugs that affect drug metabolism via cytochrome P450 should be avoided with zolpidem.
- Medicines for gastric disorders, cimetidine and ranitidine should be avoided along with zolpidem.

How to use Torzolp

- How much to use

Always take Torzolp exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

The usual dose is one Torzolp tablet (10 mg) just before bedtime.

Elderly

The usual dose is half a tablet (5mg) just before bedtime.

Patients with liver problems. The usual starting dose is half a tablet (5mg) just

before bedtime. Your doctor may decide to increase this to one tablet (10mg) if it is safe to do so.

Children and Adolescents

Torzolp should not be used in people under 18 years old.

- When to use it

- Take this medicine by mouth.
- Swallow the tablet whole with a drink of water.
- Take just before bedtime.
- Make sure you have at least 7-8 hours for sleep after taking this medicine.

- How long to use it

The treatment period should be as short as possible, from a few days to four weeks, including the tapering period.

Do not stop taking Torzolp suddenly, but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over a period of time.

The treatment should always be implemented at the lowest effective dose and maximum dosage never exceeded.

Very short treatment periods do not require any gradual treatment discontinuation.

For certain patients, it may be necessary to continue treatment for longer than four weeks, in which case careful and repeated reassessment of the patient's condition is necessary.

- If you forget to use it

Torzolp must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day. Do not take a double dose to make up for a forgotten tablet.

- If you use too much (overdose)

If you take more Torzolp than you should, tell a doctor or go to a hospital casualty department straight away.

Take the medicine pack with you. This is so the doctor knows what you have taken.

Taking too much Torzolp can be very dangerous. The following effects may happen:

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- Feeling drowsy.
- Confused.
- Sleeping deeply and possibly falling into a fatal coma.

While you are using it

- Things you must do

- Torzolp must only be taken at bedtime.
- Tell your doctor as soon as possible if you are pregnant or think you may be pregnant.

- Things you must not do

- You should not take this medicine when pregnant, unless you have discussed this with your doctor.
- You should not be given this medicine when breast-feeding, as small amounts of Torzolp can pass into breast milk.
- Do not drink alcohol while you are taking Torzolp. Alcohol can increase the effects of Torzolp and make you sleep very deeply so that you do not breathe properly or have difficulty waking.
- On the day after taking Torzolp, do not drive or use machinery or tools if you feel sleepy, dizzy or confused.

- Things to be careful of

Check with your doctor or pharmacist before taking your medicine if:

- You have a history of alcohol or drug abuse.
- You have liver problems.
- You have depression or have had another mental illnesses in the past.
- You have recently taken Torzolp or other similar medicines for more than four weeks.
- You are elderly.
- If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Torzolp.

Side effects

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

Stop taking Torzolp and see a doctor or go to a hospital straight away if:

You have an allergic reaction. The signs may include: a rash, swallowing

or breathing problems, swelling of your lips, face, throat or tongue

Tell your doctor as soon as possible if you have any of the following side effects:

- Asthenia (lack of energy).
- Ataxia (the loss of full control of bodily movements).
- Confusion.
- Euphoria (a feeling or state of intense excitement and happiness).
- Headache.
- Insomnia (difficult to sleep).
- Vertigo (sensation of feeling off balance).
- Dyspepsia (indigestion).
- Hiccup.
- Nausea.
- Arthralgia (joint pain).
- Myalgia (muscle pain).
- Upper respiratory infection.
- Diplopia (double vision).
- Vision abnormal.
- Urinary tract infection.

If any of the side effects gets serious, 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 visiting the website npra.moh.gov.my [Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Torzolp

- Storage

- Keep out of Reach of Children.
- Store below 30°C.
- Store in the original package, in order to protect from moisture.
- Do not use Torzolp after the expiry date which is stated on the carton. The expiry date refers to the last day of the month.

- 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

Yellow colored, capsule shaped tablet with “Torrent logo” debossing on one side and “10 MG” debossing on another side.

Ingredients

Active ingredient

- Zolpidem Tartrate.

Inactive ingredients

- Lactose Monohydrate (Pharmatose 200M).
- Microcrystalline Cellulose (Avicel pH 101).
- Sodium Starch Glycolate Type A (Primogel).
- Hypromellose 2910 (6 cps).
- Magnesium Stearate.
- Titanium Dioxide.
- Polyethylene Glycol 400 (PEG 400).
- Ferric Oxide Yellow.
- Ferric Oxide Red.

- MAL number:

MAL17055008AZ

Manufacturer

TORRENT PHARMACEUTICALS LTD.

Indrad 382 721, District: Mehsana INDIA.

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn Bhd.

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