

PREGEB CAPSULES

Pregabalin (75 mg, 150 mg)

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What Pregeb is used for

Pregabalin belongs to a group of medicines used to treat epilepsy, neuropathic pain, fibromyalgia and Generalised Anxiety Disorder (GAD) in adults.

How Pregeb works

Pregeb corrects chemical imbalance in brain and provides relief in epilepsy, neuropathic pain, fibromyalgia and generalised anxiety disorder.

Before you use Pregeb

- When you must not use it

Talk to your doctor or pharmacist before taking Pregeb if you experience below symptoms: -

- Some patients taking Pregeb have reported symptoms suggesting an allergic reaction, these symptoms include swelling of the face, lips, tongue, and throat, as well as diffuse skin rash.
- Pregeb has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in elderly patients. Therefore, you should be careful until you are used to any effect the medicine might have.
- Pregeb may cause blurring or loss of vision, or other changes in eyesight, many of which are temporary you should immediately tell your doctor if you experience any changes in your vision.
- Some patients with diabetes who gain weight while taking Pregabalin may need an alteration in their diabetic medicines.
- Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other

medicines to treat, for example, pain or spasticity, that have similar side effects to Pregabalin and the severity of these effects may be increased when taken together.

- There have been reports of heart failure in some patients when taking Pregeb; these patients were mostly elderly with cardiovascular conditions. Before taking this medicine you should tell your doctor if you have a history of heart disease.
- There have been reports of kidney failure in some patients when taking Pregeb. If while taking Pregeb you notice decreased urination; you should tell your doctor as stopping the medicine may improve this.

Pregnancy and lactation

Do not take Pregeb if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Pregeb, stop taking it immediately and contact your doctor.

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

- Before you start use it

You must be especially careful and talk to your doctor before taking Pregeb if any of the following apply to you.

- A small number of people being treated with anti-epileptics such as Pregeb have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- When Pregeb is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g. constipation, blocked or paralyzed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- Before taking this medicine you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence. Do not take more medicine than prescribed.
- There have been reports of convulsions when taking Pregeb or shortly after stopping Pregeb. If

you experience a convulsion, contact your doctor immediately.

- There have been reports of reduction in brain function (encephalopathy) in some patients taking Pregeb when they have other conditions. Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Pregeb and certain other medicines may influence each other (interaction). When taken with certain other medicines, Pregeb may potentiate the side effects seen with these medicines, including respiratory failure and coma. The degree of dizziness, sleepiness and decreased concentration may be increased if Pregeb is taken together with medicinal products containing: oxycodone (used as a pain-killer), lorazepam (used for treating anxiety), alcohol. Pregeb may be taken with oral contraceptives.

How to use Pregeb

- How much to use

- The usual dosage is 150-600mg per day, to be taken with or without food. Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

- For twice a day take Pregeb once in the morning and once in the evening, at about the same time each day. For three times a day take Pregeb once in the morning, once in the afternoon and once in the evening, at about the same time each day.

- How long to use it

Continue taking Pregeb for as long as your doctor recommends.

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- If you forget to use it

It is important to take your Pregeb capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Call your doctor or go to the nearest hospital emergency unit immediately. Take your box of Pregeb capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more Pregeb than you should.

While you are using it

- Things you must do

- Take Pregeb at about the same time each day.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Pregeb.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking your medicine unless your doctor tells you to.
- Do not take any new medicines without consulting your doctor.
- Do not give Pregeb 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 capsule make you feel dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Very common (may affect more than 1 in 10 people):

- Dizziness,
- Drowsiness,
- Headache.

Common (may affect up to 1 in 10 people):

- Increased appetite.
- Feeling of elation.
- Confusion.
- Disorientation.
- Decrease in sexual interest.
- Irritability.
- Disturbance in attention.
- Clumsiness.
- Memory impairment.
- Loss of memory.
- Tremor.
- Difficulty with speaking.
- Tingling feeling.
- Numbness.
- Sedation.
- Lethargy.
- Insomnia (unable to sleep or difficult to sleep).
- Fatigue.
- Feeling abnormal.
- Blurred vision, double vision.
- Vertigo, problems with balance, fall.
- Dry mouth, constipation, vomiting, flatulence, diarrhoea, nausea, swollen abdomen.
- Difficulties to erection.
- Swelling of the body including extremities.
- Feeling drunk, abnormal style of walking.
- Weight gain.
- Muscle cramp, joint pain, back pain, pain in limb.

You should seek immediate medical advice.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you get any side effect that bothers you or that does not go away.

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 npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects/ConSERF).

Storage and Disposal of Pregeb

- Storage

- Store below 30°C.
- Protect from light and moisture.
- Keep medicines out of reach of children.

- 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

Pregeb 75 mg capsules
Size '4', hard gelatin capsule having orange opaque cap and white opaque body, imprinted '1360' on cap and '75' on body with black ink containing white to off-white powder.

Pregeb 150 mg capsules
Size '1', hard gelatin capsule having white opaque cap and white opaque body, imprinted '1362' on cap and '150' on body with black ink containing white to off-white powder.

- Ingredients

Active ingredient

- Pregabalin.

Inactive ingredients

- Talc.
- StarCap 1500 Co-processed Starch which contains Starch (90%) and Starch 1500, Pregelatinised (10%).
- Hard gelatin capsule shell.

- MAL number(s):

Pregeb 75 mg capsules:
MAL*****

Pregeb 150 mg capsules:
MAL*****

Manufacturer

Torrent Pharmaceuticals Limited
Indrad 382 721, Tal: Kadi,
City: Indrad, Dist. Mehsana,
India

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Product Registration Holder

Laboratories Torrent (Malaysia) Sdn.
Bhd.
Suite E-08-08 Plaza Mont Kiara,
No. 2 Jalan Kiara Mont Kiara,
50480 Kuala Lumpur,
Malaysia.

Date of revision

21/08/2017

Serial Number

NPRA(RX/x)xxxxxx/xxxxx