PGB Pregabalin Capsules

Pregabalin 75mg Capsules

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What PGB Capsules is used for.

Neuropathic Pain

Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy

Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Generalised anxiety disorder

Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

How PGB Capsules works

PGB Capsules helps decrease the number of nerve signals, and as a result calms down overly sensitive nerve cells.

Before you use PGB Capsules

- *When you must not use it*

Do not take PGB Capsules if you:
Have

- If you are allergic to PGB Capsules or any of the other ingredients of this medicine (listed in section "Ingredients")

If you are not sure about this, talk to your doctor, pharmacist or nurse before taking this medicine.

- *Before you start to use it*

Do not take PGB Capsules if:

- If have or had depression, mood problems or suicidal thoughts or behaviour.
- If have kidney problems or get kidney dialysis
- If have heart problems including heart failure
- If have ever had swelling in your face, mouth (tongue, lips, gums) and neck (throat and larynx; angioedema)
- If have or had indigestion to milk or milk products (lactose intolerance)
- If you have diabetic, you may have higher chance of weight gain during the treatment period
- If you have vision-related problem
- Have had cases of misuse, abuse and dependence (drug-seeking behaviour) in the past
- If you have pre-existing problem related to both stomach and intestine.

Pregnancy and Lactation

It is not known if PGB Capsules will harm your unborn baby. You and your healthcare provider will have to decide if you should take PGB Capsules while you are pregnant.

It is known that PGB Capsules passes into breast milk, but it is not known if it can harm your baby. You and your healthcare provider should discuss whether you should take PGB Capsules or breast-feed, but you should not do both.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, herbal medicines and supplements.

This is because PGB Capsules may affect the way some other medicines work. Also some other medicines can affect the way PGB Capsules works.

- Any medicines that make you sleep
- PGB capsules may increase the effects of ethanol and lorazepam.
- PGB capsules appears to increase certain effects (impairment of thought process and gross bodily movements) caused by oxycodone.
- There are reports of lung failure, coma and deaths in patients taking PGB capsules and other central nervous system depressant medications.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking this medicine.

How to use PGB Capsules

- *How much to use*

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

Your doctor will prescribe a dose and treatment regimen that is right for you. The dose range is 150 to 600mg per day given in either two or three divided doses.

- *When to use it*

Take PGB Capsules exactly as prescribed. Your healthcare provider will tell you when to take PGB Capsules. It is advised to take PGB Capsules at the same time each day.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month

- *How long to use it*

Continue using PGB Capsules for the duration that the doctor recommends.

Do not stop taking PGB Capsules without checking with your healthcare provider.

If PGB Capsules is discontinued, taper the drug gradually over a minimum of 1 week rather than discontinue the drug abruptly. Talk with your healthcare

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provider about how to stop PGB Capsules slowly.

- *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. You may take the missed dose only if you leave 4 hours between doses. 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 use 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 many tablets may cause the symptoms described side effects section.

While you are using it

- *Things you must do*

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using PGB Capsules.

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

Take PGB Capsules only with a doctor's prescription.

- *Things you must not do*

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

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give PGB Capsules to anyone else, even if they have the same symptoms or condition as you.

Pregnancy, breast-feeding and fertility
Do not get pregnant while you are taking this medicine. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

- *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 dizzy and extreme sleepiness, do not drive or use machines.

Ask your healthcare provider about when it will be okay to do these activities.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any of the following side effects after using this medicine.

Very Common

- Dizziness
- Sleepiness
- Headache

Common

- Inflammatory attack of the pharynx and nasal cavities.
- Increase appetite
- Elevated mood, confused state, irritability, depression, loss in sense of direction, inability to sleep, reduced sex drive
- Lack of voluntary coordination of muscle, loss in control of posture, muscle contraction, loss of memory, memory impairment, disturbance in attention, abnormal tingling and pricking sensation, reduced sense of touch, relaxed state/reduction of irritability or agitation, balance disorder, lack of energy
- Blurry vision and double vision
- Loss of balance
- Vomiting, constipation or hard bowels, accumulation of gas in alimentary canal, accumulation of gas or air in the abdomen, dry mouth
- Muscle cramp, joint pain, back pain, pain in the limbs, tightening of muscles
- Erectile dysfunction
- Accumulation of fluid in tissues, abnormal walking, fall, feeling drunk, feeling abnormal, weakness.
- Increase weigh

Uncommon

- Level of sugar (glucose) in your blood drops too low (hypoglycaemia).
- Visual problems, eye swelling or pain.
- Sensitive to a range of sounds, finding many noises unbearable and painfully load (Hyperacusis)
- Heart problem including congestive heart failure.
- Difficulty in breathing, nosebleed, cough, nasal congestion, rhinitis, snoring, nasal dryness
- Burning or prickling sensation felt in the hands, arms, feets or any other parts of the body.
- Gastrooesophageal reflux disease,
- salivary hypersecretion
- Reduce sex drive, ejaculation delayed, painful period or breast pain.
- Blood disorders or low blood platelet count.
- Decrease weight

Rare

- Coma

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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Storage and Disposal of IBRUTINIB

- *Storage*

  Keep this medicine out of the sight and reach of children.

  Store below 30^0c

  This medicine does not require any special storage conditions.

- *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*

  PGB-75 - Pregabalin 75mg Capsules is White and Orange, hard gelatin capsules of size "4" with "I" printed on cap and "35" on body containing white to off white powder.

- *Ingredients*

  - Active ingredient

  Each hard capsule contains 75 mg of Pregabalin.

  - Inactive ingredients

  Lactose Monohydrate, Maize starch, Talc, Hard gelatin.

  - Capsule shell:

  Titanium dioxide, Red Iron oxide

- *MAL number(s):*

Manufacturer

Indoco Remedies Limited.
Plant 1, L-14, Verna Industrial Area, Verna, IN- 403722, India.

Product Registration Holder

Unimed Sdn. Bhd.,
53, Jalan Tembaga SD5/2B, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia.

Date of revision

10.01.2024

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