

Pregabalin (75 mg and 150 mg Capsules)

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What *PREGALIX* Is Used For

Pregabalin is used to treat:

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.

Fibromyalgia

Pregabalin is indicated for the management of fibromyalgia.

How *PREGALIX* works

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

Before you use *PREGALIX*

-When you must not take it

Do not start taking Pregabalin if you are allergic to pregabalin or any of the ingredients in Pregabalin. See the end of this leaflet for a complete list of ingredients in Pregabalin.

Symptoms of an allergic reaction to Pregabalin may include:

- Serious, even life-threatening allergic reactions
- Suicidal thoughts or actions
- Swelling of your hands, legs and feet
- Dizziness and sleepiness

Pregnancy and lactation

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

It is known that Pregabalin 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 Pregabalin or breast-feed, but you should not do both.

-Before you start to use *PREGALIX*

Tell your healthcare provider about all your medical conditions including if you:

- have or had depression, mood problems or suicidal thoughts or behavior
- have kidney problems or get kidney dialysis
- have heart problems including heart failure
- have a bleeding problem or a low blood platelet count
- have abused prescription medicines, or street drugs in the past
- have ever had swelling in your face, mouth (tongue, lips, gums) and neck (throat and larynx; angioedema)
- have brain malfunction (encephalopathy)
- have had cases of misuse, abuse and dependence (drug-seeking behavior) in the past
- are undergoing treatment of central neuropathic pain due to spinal cord injury
- have existing slow and ineffective breathing, or if you are taking a group of medicines called CNS depressants, including opioids

-Taking other medicines

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins or herbal supplements. Pregabalin and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- Angiotension converting enzyme (ACE) inhibitors, which are used to treat many conditions, including high

blood pressure.

You may have a higher chance for swelling and hives if these medicines are taken with Pregabalin. See Section 5 "While you are using Pregabalin".

Avandia (rosiglitazone), Avandia (contains rosiglitazone and metformin), or Actos (pioglitazone) for diabetes. You may have a higher chance of weight gain or swelling of your hands or feet if these medicines are taken with Pregabalin. See Section 6. Side Effects.

Any medicines that make you sleepy.

Pregabalin may increase the effects of ethanol and lorazepam.

Pregabalin 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 Pregabalin and other central nervous system depressant medications, including in patients who are drug abusers.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist each time you get a new medicine. Do not start a new medicine without talking to your healthcare provider.

How to use *PREGALIX*

-How much to take

Take Pregabalin exactly as prescribed. Your healthcare provider will tell you how much Pregabalin to take.

Pregabalin may be taken with or without food.

Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.

The dose range is 150 to 600 mg per day given in either two or three divided doses.

-When to take it

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

-How long to use it

Do not stop taking Pregabalin without checking with your healthcare

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Consumer Medication Information Leaflet (RiMUP)

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provider. If you stop taking Pregalix suddenly, you may have trouble sleeping, nausea, headaches, anxiety, excessive sweating, and diarrhea. If you have epilepsy and you stop taking Pregalix suddenly, you may have seizures more often.

If Pregalix is discontinued, taper the drug gradually over a minimum of 1 week rather than discontinue the drug abruptly. Talk with your healthcare provider about how to stop Pregalix slowly.

-If you forget to take it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. Do not take two doses at the same time.

-If you take too much (overdose)

If you take too much Pregalix, call your healthcare provider or poison control center, or go to the nearest emergency room right away.

These side effects were reported when Pregalix was taken too much:

Affective disorder (abnormal disturbances of mood), sleepiness, confusion, depression, agitation and restlessness.

Fits (seizures) were also reported when the medicine was taken in overdose.

While you are using it

-Things you must do

Stop taking Pregalix and call your healthcare provider immediately if you have any of these signs of a serious allergic reaction:

- Swelling of your face, mouth, lips, gums, tongue, throat or neck
- Trouble breathing
- Rash, hives (raised bumps) or blisters

Call your healthcare provider immediately if you have any of these symptoms, especially if they are new, worse or worry you:

- Thoughts about suicide or dying
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling agitated or restless
- Panic attacks

- Trouble sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking (mania)
- Other unusual changes in behavior or mood

-Things you must not do

Pregabalin may cause dizziness and extreme sleepiness which may impair the ability to perform tasks such as driving or operating machinery and could increase the occurrence of accidental injury (fall) in the elderly population.

Do not drive a car, work with machines, or do other dangerous activities until you know how Pregalix affects you. Ask your healthcare provider about when it will be okay to do these activities.

-Things to be careful of

If you have suicidal thoughts or actions, do not stop Pregalix without first talking to a healthcare provider.

- Stopping Pregalix suddenly can cause serious problems
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Side effects

Very Common:

- Dizziness, sleepiness
- Headache

Common:

- Cold
- Increased 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
- Accumulation of fluid in tissues, abnormal walking, fall, feeling drunk, feeling abnormal, weakness
- Increased weight
- Diarrhea, vomiting

If you have diabetes, you should pay attention to your skin while taking Pregalix and tell your healthcare provider about any sores or skin problems.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of Pregalix. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects.

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 Medicinal Problems/Side Effects/AEFI).

Storage and disposal of PREGALIX

-Storage

Store Pregalix capsules below 30°C. Keep in a cool, dry place away from sunlight.

-Disposal

Safely throw away any Pregalix that is out of date or no longer needed. Keep Pregalix and all medicines out of the reach of children.

PREGALIX CAPSULES

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Pregabalin (75 mg and 150 mg Capsules)

Product Description

-What it looks like

Pregalix 75 mg capsules:

Opaque white/ Orange Opaque size “4” Hard gelatin capsules radially imprinted with ‘A’ on cap and ‘142’ on body with black ink filled with white to off white powder.

Pregalix 150 mg capsules:

Opaque white/ opaque white size “2” Hard gelatin capsules radially imprinted with ‘A’ on cap and ‘144’ on body with black ink filled with white to off white powder.

-Ingredients

Active ingredient:

- Pregabalin

Inactive ingredients:

- Black imprinting ink
- Capsule content: Pregelatinized Starch (Starch 1500 LM), Talc
- Capsule shell (75mg): Gelatin, Water, Iron Oxide Red, Titanium Dioxide
- Capsule shell (150mg): Gelatin, Water, Titanium Dioxide

-MAL number

PREGALIX CAPSULES 75mg

MALxxxxxxxAZ

PREGALIX CAPSULES 150mg

MALxxxxxxxAZ

Manufacturer

Alembic Pharmaceuticals Limited
(Formulation Division),
At- Panelav, Tal- Halol,
City: Panelav,
Dist: Panchmahal, Gujarat
State, India.

Product Registration Holder

Genpharma Sdn. Bhd.
Lot 5016, Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia.

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