

PREGATAS 75 and PREGATAS 150

(Pregabalin Capsules 75 mg and 150mg)

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What Pregatas is used for

Pregatas 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.

Fibromyalgia

Pregabalin is indicated for the management of fibromyalgia.

How Pregatas works

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

Before you use Pregatas

When you must not take it

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

Symptoms of an allergic reaction to Pregatas 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

Animal studies have shown that pregabalin, the active ingredient in pregabalin, causes reproductive toxicity. Hence, it should not be taken during pregnancy. Effective contraception must be used in women of child bearing potential.

Pregabalin is excreted in the milk of lactating women. As the safety of pregabalin in infants is not known, breast-feeding is not recommended during treatment with pregabalin.

You and your healthcare provider should discuss whether you should take pregabalin or breast-feed, but you should not do both.

- *Before you start use it*

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

- have or had depression, mood problems or suicidal thoughts or behaviour.
- 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, street drugs, or alcohol in the past
- have ever had swelling in your face, mouth, tongue, lips, gums, neck or throat (angioderma).

- are in the first trimester of pregnancy as Pregatas may cause major birth defects in the unborn child.
- have or had indigestion to milk or milk products (lactose intolerance)
- 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 nonprescription medicines, vitamins or herbal supplements.

Pregatas 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 Pregatas. See Section “*When you must not take it*”.
- Avandia (rosiglitazone), Avandamet (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 Pregatas. See Section Side Effects.

- Any medicines that make you sleepy

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- 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 with your healthcare provider.

How to take Pregatas

- How much to take

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

- Pregatas 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 use it

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

- How long to take it

Do not stop taking Pregatas without checking with your

healthcare provider. If you stop taking Pregatas suddenly you may have headaches, nausea, diarrhoea or trouble sleeping. If you have epilepsy and you stop taking Pregatas suddenly, you may have seizures more often. Talk with your healthcare provider about how to stop Pregatas 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 Pregatas, call your healthcare provider or poison control center, or go to the nearest emergency room right away.

These side effects were reported when Pregatas 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 Pregatas 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
- Trouble sleeping (insomnia)
- Attempts to commit suicide
- New or worse irritability
- New or worse depression
- Acting aggressive, being angry or violent
- New or worse anxiety
- Acting on dangerous impulses
- Feeling agitated or restless
- An extreme increase in activity and talking (mania)
- Panic attacks
- Other unusual changes in behaviour or mood

- Things you must not do

Do not drive a car, work with machines, or do other dangerous activities until you know how Pregatas affects you.

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

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.

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 Pregatas without first talking to a healthcare provider.

- Stopping Pregatas 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

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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, behaviours, 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 Pregatas 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 Pregatas. 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 Pregatas

Storage

Keep out of the reach and sight of children.

Store below 30 °C.

- Disposal

Safely throw away any Pregatas that is out of date or no longer needed.

Keep Pregatas and all medicines out of the reach of children.

Product Description

- What it looks like

75 mg: Red opaque/ White opaque, size “4” hard gelatin capsules imprinted with ‘PG’ on cap and ‘75’ on body containing white to off white powder.

150 mg: White opaque/ White opaque, size “2” hard gelatin

capsules imprinted with ‘PG’ on cap and ‘150’ on body containing white to off white powder.

- Ingredients

- Active ingredient(s)

Pregabalin

- Inactive ingredients

Pregelatinized starch (Starch 1500)

Purified Talc

Capsule Shell:

Gelatin,

Purified water,

Sodium Lauryl Sulphate,

Titanium dioxide (E 171)

Iron Oxide Red (E 172) – for 75 mg only

Printing ink:

Shellac,

Dehydrated alcohol,

Isopropyl Alcohol,

Butyl Alcohol,

Propylene Glycol,

Strong Ammonia Solution,

Black Iron Oxide,

Potassium Hydroxide,

Purified Water.

- Registration number(s):

Product Name

Registration Number

Pregatas 75: MALXXXXXXXXXA

Pregatas 150: MALXXXXXXXXXA

Manufacturer

Intas Pharmaceuticals Limited.
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Product Registration Holder

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