

PREGAVID CAPSULES

Pregabalin (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg Capsules)

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What Pregavid Capsules is used for

Pregavid Capsules 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 generalization.

Generalized anxiety disorder

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

Fibromyalgia

Pregabalin is indicated for the management of fibromyalgia.

How Pregavid Capsules works

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

Before you use Pregavid Capsules

- When you must not use it

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

Symptoms of an allergic reaction to Pregavid Capsules 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 Pregavid Capsules, causes reproductive toxicity. Hence it should not be taken during pregnancy. Effective contraception must be used in women of child bearing potential.

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

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

- Before you start to use it

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)
- Are in the first trimester of pregnancy as Pregavid Capsules 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 non-prescription medicines, vitamins or herbal supplements. Pregavid Capsules and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- Angiotensin converting enzyme (ACE) inhibitors, which are used to treat high blood pressure. You may have a higher chance for swelling and hives if these medicines are taken with Pregavid Capsules.
- 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 Pregavid Capsules.
- Any medicines that make you sleepy.
- Pregavid Capsules may increase the effects of ethanol and lorazepam.
- Pregavid 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 Pregavid Capsules 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

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each time you get a new medicine. Do not start a new medicine without talking to your healthcare provider.

How to use Pregavid 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.

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

Use as directed by your doctor or pharmacist.

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

- How long to use it

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

Do not stop taking Pregavid Capsules without checking with your healthcare provider. If you stop taking Pregavid Capsules suddenly, you may have trouble sleeping, nausea, headaches, anxiety, excessive sweating, and diarrhea. If you have epilepsy and you stop taking Pregavid Capsules suddenly, you may have seizures more often.

If Pregavid Capsules 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 Pregavid Capsules slowly.

- If you forget to use it

If you missed 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 use too much (overdose)

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

These side effects were reported when Pregavid Capsules was taken too much:

- Affective disorder (abnormal disturbances of mood), sleepiness, confusion, depression, agitation and restlessness.
- Fit (seizures) were also reported when the medicine was taken in overdose.

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 Pregavid Capsules.

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

Take Pregavid Capsules only with a doctor's prescription.

Stop taking Pregavid Capsules 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

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 Pregavid Capsules to anyone else, even if they have the same symptoms or condition as you.

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

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 Pregavid Capsules without first talking to a healthcare provider.

- Stopping Pregavid Capsules suddenly can cause serious problems

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- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check 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

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

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

Very Common:

- Dizziness, sleepiness
- Headache

Common:

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

If you have diabetes, you should pay attention to your skin while taking Pregavid Capsules 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 Pregavid Capsules. 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 visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Pregavid Capsules

- Storage

Keep out of the reach and sight of children.

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

- 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

Pregavid Capsules 25mg

Size 4 capsule with white opaque cap and white opaque body, printed with “hovid” on cap and “PB 25” on body

in black ink, containing white to off-white powder.

Pregavid Capsules 50mg

Size 2 capsule with white opaque cap and white opaque body, printed with “hovid” on cap and “PB 50” on body in black ink, containing white to off-white powder. The body is also marked with a black band.

Pregavid Capsules 75mg

Size 4 capsule with brown opaque cap and white opaque body, printed with “hovid” on cap and “PB 75” on body in black ink, containing white to off-white powder.

Pregavid Capsules 100mg

Size 4 capsule with light brown opaque cap and light brown opaque body, printed with “hovid” on cap and “PB 100” on body in black ink, containing white to off-white powder. The body is also marked with a black band.

Pregavid Capsules 150mg

Size 2 capsule with white opaque cap and white opaque body, printed with “hovid” on cap and “PB 150” on body in black ink, containing white to off-white powder.

Pregavid Capsules 200mg

Size 1 capsule with light orange opaque cap and light orange opaque body, printed with “hovid” on cap and “PB 200” on body in black ink, containing white to off-white powder.

Pregavid Capsules 225mg

Size 1 capsule with light brown opaque cap and white opaque body, printed with “hovid” on cap and “PB 225” on body in black ink, containing white to off-white powder.

Pregavid Capsules 300mg

Size 0 capsule with brown opaque cap and white opaque body, printed with “hovid” on cap and “PB 300” on body in black ink, containing white to off-white powder.

- Ingredients

- Active ingredient
Pregabalin

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Consumer Medication Information Leaflet (RiMUP)

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- Inactive ingredients
 - Partially Pregelatinised Starch
 - Talc

- MAL numbers:
 - Pregavid Capsules 25mg
MALxxxxxxxxAZ

 - Pregavid Capsules 50mg
MALxxxxxxxxAZ

 - Pregavid Capsules 75mg
MAL24046009AZ

 - Pregavid Capsules 100mg
MAL24046008AZ

 - Pregavid Capsules 150mg
MAL24046007AZ

 - Pregavid Capsules 200mg
MAL24046006AZ

 - Pregavid Capsules 225mg
MAL24046005AZ

 - Pregavid Capsules 300mg
MAL24046004AZ

Manufacturer

Hovid Berhad
Lot 56442 7 ½ Miles
Jalan Ipoh/Chemor,
31200 Ipoh, Perak,
Malaysia.

Marketing Authorization Holder/

Product Registration Holder

(Malaysia)/ Product Owner

Hovid Berhad
121, Jalan Tunku Abdul Rahman,
(Jalan Kuala Kangsar)
30010 Ipoh, Perak,
Malaysia.

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