# EPIBALIN HARD CAPSULES

Pregabalin (75 mg, 150 mg, 300 mg)

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**What EPIBALIN is used for**

EPIBALIN 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 EPIBALIN works**

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

**Before you use EPIBALIN**

- *When you must not use it*

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

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

EPIBALIN is excreted in the milk of lactating women. As the safety of EPIBALIN in infants is not known, breast-feeding is not recommended during treatment with EPIBALIN. You and your healthcare provider should discuss whether you should take EPIBALIN or breast-feed, but you should not do both.

- *Before you start to take 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 EPIBALIN may cause major birth defects in the unborn child.
- 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. EPIBALIN 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 many conditions, including high blood pressure. You may have a higher chance for swelling and hives if these medicines are taken with EPIBALIN. See Section 5 “While you are using EPIBALIN”.
- 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 EPIBALIN. See Section 6. “Side Effects”.
- Any medicines that make you sleepy.
- EPIBALIN may increase the effects of ethanol and lorazepam.
- EPIBALIN appears to increase

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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 EPIBALIN 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 EPIBALIN**
- *How much to use*

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

- *How long to use it*

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

- *If you forget to use 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 use too much (overdose)*

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

  These side effects were reported when EPIBALIN 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 EPIBALIN**
- *Things you must do*

  **Stop taking EPIBALIN 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 drive a car, work with machines, or do other dangerous activities until you know how EPIBALIN 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 EPIBALIN without first talking to a healthcare provider**.
  - Stopping EPIBALIN 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**

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**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

**Rare:**
- Stevens-Johnson syndrome

If you have diabetes, you should pay attention to your skin while taking EPIBALIN 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 EPIBALIN. 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.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)

**Storage and Disposal of EPIBALIN**
- *Storage*

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

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

**Product Description**
- *What it looks like*

*75 mg hard capsules*
White to off white colour granular powder filled in size “4” hard gelatin capsules with white opaque body imprinted “PGBN” and light blue opaque cap imprinted “75” with black ink

*150 mg hard capsules*
White to off white colour granular powder filled in size “2” hard gelatin capsules with white opaque body imprinted “PGBN” and light blue opaque cap imprinted “150” with black ink

*300 mg hard capsules*
White to off white colour granular powder filled in size “0” hard gelatin capsules with white opaque body imprinted “PGBN” and light blue opaque cap imprinted “300” with black ink

- *Ingredients*
  - Active ingredient
    Pregabalin

  - Inactive ingredients

*Capsules content*:
Mannitol (E421), Talc

*Capsules shell*:
Gelatin, Titanium dioxide (E171), FD & C Blue 2, Purified water

*Printing Ink*:
Shellac (E904), Black iron oxide (E172), Ammonia Solution, concentrated (E527), Potassium hydroxide (E525), Propylene glycol (E1520)

- *MAL number:*

EPIBALIN 50 mg Capsules- XXXXXXX
EPIBALIN 75 mg Capsules- XXXXXXX
EPIBALIN 150 mg Capsules- XXXXXXX

**Manufacturer**
MSN Laboratories Private Limited, Formulations Division Unit-II, Survey. Nos. 1277 & 1319 to 1324, Nandigama Village & Mandal, Rangareddy District, Telangana, 509228 India

**Product Registration Holder**
Synercam (M) Sdn Bhd,
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Malaysia

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