

# PG-LIN 75

Pregabalin Capsules 75 mg

Consumer Medication Information Leaflet (RiMUP)

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## What is PG-LIN 75 used for

PG-LIN 75 belongs to a group of medicines used to treat epilepsy, neuropathic pain and Generalised Anxiety Disorder (GAD) and *Fibromyalgia* in adults.

### *Neuropathic pain*

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

### *Epilepsy*

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

### *Generalised anxiety disorder*

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

### *Fibromyalgia*

Pregabalin is indicated for the management of fibromyalgia.

## How PG-LIN 75 works

Pregabalin binds to an auxiliary subunit ( $\alpha 2-\delta$  protein) of voltage-gated calcium channels in the central nervous system.

## Before you use PG-LIN 75

### -When you must not use it

Do not start taking PG-LIN 75 if you have hypersensitivity to the active substance or to any of the excipients used in PG-LIN 75.

See the end of this leaflet for a complete list of ingredients in PG-LIN 75.

### -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 behaviour
- 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 (angiodema)
- plan to father a child.
- have brain malfunction (encephalopathy)
- cases of misuse, abuse and dependence have been reported
- caution should be exercised in patients with a history of substance abuse and the patient should be monitored for symptoms of pregabalin misuse, abuse or dependence (drug seeking behaviour)
- patients undergoing treatment of central neuropathic pain due to spinal cord injury.
- **are pregnant or plan to become pregnant. It is not known if PG-LIN 75 will harm your unborn baby.** You and your healthcare provider will have to decide if you should take PG-LIN 75 while you are pregnant
- **are breastfeeding. It is not known if PG-LIN 75 passes into breast milk and if it can harm your baby.** You and your healthcare provider should discuss whether you should take PG-LIN 75 or breastfeed, but you should not do both.

### -Taking other medications:

**Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins or herbal supplements. PG-LIN 75 and other medicines may affect each other causing side effects.**

### -Oral contraceptives, norethisterone and/or ethinyl oestradiol

Co-administration of pregabalin with the oral contraceptives norethisterone and/or ethinyl oestradiol does not influence the steady-state pharmacokinetics of either substance.

### -Central nervous system influencing medical products

Pregabalin may potentiate the effects of ethanol and lorazepam

## PG-LIN 75 with food and drink:

PG-LIN 75 can be taken with or without food.

It is advised not to drink alcohol while taking PG-LIN 75.

## Pregnancy, breast-feeding and fertility:

PG-LIN 75 should not be taken during pregnancy or when breast-feeding, unless you are told otherwise by your doctor.

Effective contraception must be used by women of child-bearing potential. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## PG-LIN 75 contains lactose monohydrate

If you have been told by your doctor that you have intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

## How to use PG-LIN 75

### -How much to use

- Take PG-LIN 75 exactly as prescribed. Your healthcare provider

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will tell you how much PG-LIN 75 to take.

- PG-LIN 75 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.

## **Neuropathic pain**

Pregabalin treatment can be started at a dose of 150 mg per day given as two or three divided doses. Based on individual patient response and tolerability, the dose may be increased to 300 mg per day after an interval of 3 to 7 days, and if needed, to a maximum dose of 600 mg per day after an additional 7-day interval.

## **Epilepsy**

Pregabalin treatment can be started with a dose of 150 mg per day given as two or three divided doses. Based on individual patient response and tolerability, the dose may be increased to 300 mg per day after 1 week. The maximum dose of 600 mg per day may be achieved after an additional week.

## **Generalised anxiety disorder**

The dose range is 150 to 600 mg per day given as two or three divided doses. The need for treatment should be reassessed regularly.

Pregabalin treatment can be started with a dose of 150 mg per day. Based on individual patient response and tolerability, the dose may be increased to 300 mg per day after 1 week. Following an additional week, the dose may be increased to 450 mg per day. The maximum dose of 600 mg per day may be achieved after an additional week.

## **Fibromyalgia**

The usual dose range for most patients is 300 to 450 mg per day given in two divided doses. Some patients may derive additional benefit at 600 mg per day. Dosing should begin at 75 mg two times a day (150 mg/day) and may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg/day may be further increased to 225 mg two times a day (450 mg/day). If needed, in some patients, based on individual response and tolerability, the dose may be increased to maximum dosage of 600 mg/day after an additional week.

### -When to use it

Take PG-LIN 75 exactly as prescribed.

Your healthcare provider will tell you when to take PG-LIN 75. It is advised to take PG-LIN 75 at the same times each day.

### -How long to use it

Do not stop taking PG-LIN 75 without checking with your healthcare provider. If you stop taking PG-LIN 75 suddenly you may have headaches, nausea, diarrhoea or trouble sleeping. If you have epilepsy and you stop taking PG-LIN 75 suddenly, you may have seizures more often. Talk with your healthcare provider about how to stop PG-LIN 75 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 PG-LIN 75, call your healthcare provider or poison

control center, or go to the nearest emergency room right away.

These side effects were reported when PG-LIN 75 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 PG-LIN 75 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

#### **Driving and using machines**

PG-LIN 75 may produce dizziness, sleepiness and decreased concentration.

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You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

## -Things to be careful of

If you have suicidal thoughts or actions, do not stop PG-LIN 75 without first talking to a healthcare provider.

- Stopping PG-LIN 75 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, somnolence, headache

### **Common:**

- Nasopharyngitis
- Appetite increased
- Euphoric mood, confusion, irritability, disorientation, insomnia, libido decreased
- Ataxia, coordination abnormal, tremor, slurred speech, loss or disturbance of memory, memory impairment, disturbance in attention, burning or prickling sensation, reduced sense of touch or sensation, sedation, balance disorder, lethargy
- Vision blurred, diplopia
- Vertigo

- Vomiting, nausea, constipation, diarrhoea, flatulence, abdominal distension, dry mouth
- Muscle cramp, joint pain, back pain, pain in limb, cervical spasm
- Erectile dysfunction
- Oedema peripheral, oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue
- Weight increased

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

## **Storage and Disposal of PG-LIN 75**

### -Storage

Store below 30°C.

Keep the medicine out of reach of children.

### -Disposal

- Safely throw away any PG-LIN 75 that is out of date or no longer needed
- Keep PG-LIN 75 and all medicines out of the reach of children.

## **Product Description**

### -What it looks like

Dark Orange/white coloured hard gelatine capsules size “2” filled with white granular powder.

### -Ingredients

- Active ingredient(s)  
Pregabalin
- Inactive ingredient(s)  
Lactose Monohydrate NF316  
Talc  
Maize Starch  
Size “2” dark Orange/white hard gelatin capsule shell

### -MAL number

MAL20116013AZ

## **Manufacturer**

Gracure Pharmaceuticals Ltd.  
E-1105, Industrial Area,  
Phase-III, Bhiwadi, Alwar District,  
Rajasthan 301019, India

## **Product Registration Holder**

Synercam (M) Sdn. Bhd. A-17-7,  
BLOCK A, JAYA ONE, NO. 72A,  
JALAN PROFESOR DIRAJA  
UNGKU AZIZ, SEKSYEN 13,  
46200 PETALING JAYA

MALAYSIA

## **Date of revision**

04/09/2024

## **Serial Number**

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