

# PREGABALIN SANDOZ CAPSULES

Consumer Medication Information Leaflet (RiMUP)

Pregabalin (50mg, 75mg & 150mg capsules)

## WHAT IS IN THIS LEAFLET:

1. What is PREGABALIN SANDOZ used for
2. How PREGABALIN SANDOZ works
3. Before you use PREGABALIN SANDOZ
4. How to use PREGABALIN SANDOZ
5. While you are using it
6. Side effects
7. Storage and disposal of PREGABALIN SANDOZ
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## WHAT IS PREGABALIN SANDOZ USED FOR

PREGABALIN SANDOZ 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 PREGABALIN SANDOZ WORKS

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

## BEFORE YOU USE PREGABALIN SANDOZ

### When you must not use it

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

Symptoms of an allergic reaction to Pregabalin Sandoz may include:

- Serious, even life-

threatening allergic reactions

- Suicidal thoughts or actions
- Swelling of your hands, legs and feet
- Dizziness and sleepiness

### Before you start use it

You should inform your doctor if you have or had any of the following conditions:

- depression, mood problems or suicidal thoughts or behavior
- kidney problems or get kidney dialysis
- heart problem including heart failure
- bleeding problem or a low blood platelet count
- abuse of prescription medicines, street drugs, or alcohol in the past
- swelling in your face, mouth, tongue, lips, gums, neck or throat (angioedema)

### ***Pregnancy and breast-feeding***

#### *Pregnancy*

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Pregabalin Sandoz. It is not known if Pregabalin Sandoz will harm your unborn baby. You and your healthcare provider will have to decide if you should take Pregabalin Sandoz while you are pregnant.

#### *Breast-feeding*

It is not known if Pregabalin Sandoz passes into breast milk and if it can harm your baby. You and your healthcare provider should discuss whether you should take Pregabalin Sandoz or breast-feed, but you should not do both.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregabalin Sandoz and certain other medicines may influence each other causing side effects. Especially tell your doctor if you take:

- Angiotensin converting enzyme (ACE) inhibitors

- Oxycodone – (used as a pain-killer)
- Lorazepam – (used for treating anxiety)
- Alcohol

### Taking Pregabalin Sandoz with food and drink

Pregabalin Sandoz capsules may be taken with or without food.

## HOW TO USE PREGABALIN SANDOZ

### How much to use

Treatment with PREGABALIN is usually started with a small dose which is gradually increased to a dose that has the best result for you. Always take Pregabalin Sandoz exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will determine what dose is appropriate for you.

### When to use it

Take Pregabalin Sandoz exactly as prescribed. Your doctor will tell you when to take Pregabalin Sandoz. It is advised to take Pregabalin Sandoz at the same times each day.

### How long to use it

Do not stop taking Pregabalin Sandoz without checking with your doctor. If you stopped taking Pregabalin Sandoz suddenly, you may have headaches, nausea, diarrhoea or trouble sleeping. If you have epilepsy and you stop taking Pregabalin Sandoz suddenly, you may have seizures more often. Talk with your doctor about how to stop Pregabalin Sandoz slowly.

### If you forget to use it

It is important to take your medicine every day. However, if you forget to take one or more doses, take another as soon as you remember and then go on as prescribed. Do not take a double dose.

### If you use too much (overdose)

If you take too much Pregabalin Sandoz, call your doctor or go to the nearest hospital emergency unit immediately.

## WHILE YOU ARE USING IT

### Things you must do

# PREGABALIN SANDOZ CAPSULES

Consumer Medication Information Leaflet (RiMUP)

Pregabalin (50mg, 75mg & 150mg capsules)

Stop taking Pregabalin Sandoz and call your doctor 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 doctor 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
- Difficulty breathing

### Things you must not do

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

Do not drink alcohol while taking Pregabalin Sandoz. Pregabalin Sandoz and alcohol can affect each other and increase side effects such as sleepiness and dizziness.

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor.

Do not give Pregabalin Sandoz to anyone else, even if they have the same symptoms or condition as you.

### Things to be careful of

If you have suicidal thoughts or actions, do not stop Pregabalin Sandoz without first talking to a doctor.

- Stopping Pregabalin Sandoz 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 doctor 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 doctor between visits as needed, especially if you are worried about symptoms.

### **SIDE EFFECTS**

The most common side effects of Pregabalin Sandoz include:

- Dizziness
- Headache
- Trouble concentrating
- Blurry vision
- Swelling of hands and feet
- Weight gain
- Dry mouth
- Insomnia

Pregabalin Sandoz caused skin sores in animal studies. Skin sores did not happen in studies in people. If you have diabetes, you should pay attention to your skin while taking Pregabalin Sandoz and tell your doctor about any sores or skin problems.

Contact your doctor immediately or go to the Emergency department of your nearest hospital if you are experiencing breathing problems such as slow, shallow or weak breathing after taking this medicine as this can be a sign of respiratory depression.

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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](http://npra.gov.my) [Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### **STORAGE AND DISPOSAL OF PREGABALIN SANDOZ**

#### Storage

Store below 30°C.

Store in the original pack, in order to protect the contents from moisture. Keep all medicines out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the outer carton.

#### Disposal

The medicine must 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

#### **Pregabalin Sandoz 50mg**

Hard-gelatine capsule size 3 with white to nearly white coloured powder as filling mass.

Capsule shell top part (cap) - White opak, axial: black imprinting "P"; Capsule shell bottom part (body) - White opak, axial: black imprinting: "50".

#### **Pregabalin Sandoz 75mg**

Hard-gelatine capsule size 4 with white to nearly white coloured powder as filling mass.

Capsule shell top part (cap) - Swedish orange opak, axial: black imprinting "P"; Capsule shell bottom part (body) - White opak, axial: black imprinting: "75".

#### **Pregabalin Sandoz 150mg**

Hard-gelatine capsule size 2 with white to nearly white coloured powder as filling mass.

Capsule shell top part (cap) - White opak, axial: black imprinting "P"; Capsule shell bottom part (body) - White opak, axial: black imprinting: "150".

#### Ingredients

#### Active ingredients

The active substance is Pregabalin.

# PREGABALIN SANDOZ CAPSULES

Consumer Medication Information Leaflet (RiMUP)

Pregabalin (50mg, 75mg & 150mg capsules)

---

Each hard capsule contains:

***Pregabalin Sandoz 50mg***

50mg pregabalin

***Pregabalin Sandoz 75mg***

75mg pregabalin

***Pregabalin Sandoz 150mg***

150mg pregabalin

## Inactive Ingredients

Black imprinting ink

Capsule content: Maize Starch,

Pregelatinized Starch, Talc

Capsule shell: titanium dioxide (E

171), gelatin

## - MAL NO.

***Pregabalin Sandoz 50mg***

MAL17107018AZ

***Pregabalin Sandoz 75mg***

MAL17107019AZ

***Pregabalin Sandoz 150mg***

MAL17107020AZ

## MANUFACTURER & PRODUCT REGISTRATION HOLDER

### Manufacturer

Salutas Pharma GmbH

Otto-von-Guericke Allee 1

39179 Barleben

Germany

### Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.

Unit 1202, Level 12, Uptown 1,

No. 1, Jalan SS 21/58, Damansara Uptown,

47400 Petaling Jaya, Selangor, Malaysia

## DATE OF REVISION

FEB 2024

## SERIAL NUMBER

NPRA(R2/2)210821/733