

## Package leaflet: Information for the patient

### PREGABANEURINE 75 mg hard capsules

Pregabalin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What PREGABANEURINE is and what it is used for ?
2. What you need to know before you use PREGABANEURINE ?
3. How to use PREGABANEURINE ?
4. Possible side effects
5. How to store PREGABANEURINE ?
6. Contents of the pack and other information

#### 1. What PREGABANEURINE is and what it is used for?

PREGABANEURINE belongs to a group of medicines used to treat epilepsy, neuropathic pain and Generalised Anxiety Disorder (GAD) in adults.

**Peripheral and central neuropathic pain:** PREGABANEURINE is used to treat long lasting pain caused by damage to the nerves. A variety of diseases can cause peripheral neuropathic pain, such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles. Peripheral and central neuropathic pain may also be associated with mood changes, sleep disturbance, fatigue (tiredness) and can have an impact on physical and social functioning and overall quality of life.

**Epilepsy:** PREGABANEURINE is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation) in adults. Your doctor will prescribe PREGABANEURINE for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take PREGABANEURINE in addition to your current treatment. PREGABANEURINE is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

**Generalised Anxiety Disorder:** PREGABANEURINE is used to treat Generalised Anxiety Disorder (GAD). The symptoms of GAD are prolonged excessive anxiety and worry that are difficult to control. GAD can also cause restlessness or feeling keyed up or on edge, being easily fatigued (tired), having difficulty concentrating or mind going blank, feeling irritable, having muscle tension or sleep disturbance. This is different to the stresses and strains of everyday life.

#### 2. What you need to know before you take PREGABANEURINE ?

##### Do not take PREGABANEURINE:

- If you are allergic to pregabalin or any of the other ingredients of this medicine (listed in section 6).

##### Warnings and precautions

Talk to your doctor or pharmacist before taking PREGABANEURINE.

- Some patients taking PREGABANEURINE have reported symptoms suggesting an allergic reaction. These symptoms include swelling of the face, lips, tongue, and throat, as well as diffuse skin rash. Should you experience any of these reactions, you should contact your physician immediately.
- - Serious skin rashes, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with pregabalin. Stop taking pregabalin and see a doctor straight away if you notice any of the symptoms associated with these serious skin reactions described in section 4.
- PREGABANEURINE has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in elderly patients. Therefore, you should be careful until you are used to any effect the medicine might have.
- PREGABANEURINE may cause blurring or loss of vision or other changes in eyesight, many of which are temporary. You should immediately tell your doctor if you experience any changes in your vision.
- Some patients with diabetes who gain weight while taking pregabalin may need an alteration in their diabetic medicines.
- Some side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to pregabalin and the severity of these effects may be increased when taken together.
- There have been reports of heart failure in some patients when taking PREGABANEURINE; these patients were mostly elderly with cardiovascular conditions. **Before taking this medicine you should tell your doctor if you have a history of heart disease.**
- There have been reports of kidney failure in some patients when taking PREGABANEURINE. If while taking PREGABANEURINE you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.
- A small number of people being treated with anti-epileptics such as PREGABANEURINE have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- - Gastrointestinal problems may occur (eg constipation, blocked or paralyzed bowel movement) when PREGABANEURINE is used with other medicines that can cause constipation (such as certain classes of pain medicines). Tell your doctor if you suffer from constipation, especially if you are prone to this problem. Before taking this medicine you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence. Do not take more medicine than prescribed.
- There have been reports of convulsions when taking PREGABANEURINE or shortly after stopping PREGABANEURINE. If you experience a convulsion, contact your doctor immediately.
- There have been reports of reduction in brain function (encephalopathy) in some patients taking PREGABANEURINE when they have other conditions. Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease.
- - Cases of breathing difficulties have been reported. If you suffer from a neurological or respiratory disease, kidney failure, or are over 65, your doctor may prescribe appropriate doses. Contact your doctor if you have difficulty breathing or if your breathing seems shallow.

### Addiction:

Some people may become addicted to PREGABANEURINE (need to keep taking the medicine). They may experience withdrawal effects when they stop taking PREGABANEURINE (see section 3, “How to take PREGABANEURINE?” and “If you stop taking PREGABANEURINE”). If you are concerned that you may become dependent on PREGABANEURINE, it is important that you consult your doctor. If you notice any of the following signs during your treatment with PREGABANEURINE, it may be a sign that you have become dependent:

- You need to take the medicine for longer than your doctor has advised.
- You feel the need to take a larger dose than recommended.
- You are using the medicine for reasons other than those for which it was prescribed.
- You have tried several times without success to stop or control the use of this medicine.
- When you stop taking the medicine, you feel bad, and you feel better when you start taking it again.

If you notice any of these symptoms, talk to your doctor to discuss the best treatment option for you, including when to stop treatment and how to do so safely.

### **Children and adolescents**

The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, pregabalin should not be used in this age group.

### **Other medicines and PREGABANEURINE**

Tell your doctor pharmacist if you are taking, have recently taken or might take any other medicines.

PREGABANEURINE and certain other medicines may influence each other (interaction). When taken with certain other medicines, PREGABANEURINE may potentiate the side effects seen with these medicines, including respiratory failure and coma. The degree of dizziness, sleepiness and decreased concentration may be increased if PREGABANEURINE is taken together with medicines containing:

Oxycodone - (used as a pain-killer)

Lorazepam - (used for treating anxiety)

Alcohol

PREGABANEURINE may be taken with oral contraceptives.

### **PREGABANEURINE with food, drink and alcohol**

PREGABANEURINE capsules may be taken with or without food.

It is advised not to drink alcohol while taking PREGABANEURINE.

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

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

Use of pregabalin during the first 3 months of pregnancy may cause birth defects in the unborn child which require medical treatment. In a study looking at data from women from the Nordic countries who took pregabalin during the first 3 months of pregnancy, 6 out of 100 babies had such birth defects. This figure compares to 4 out of 100 babies born to women not treated with pregabalin during the study. Abnormalities of the face (orofacial clefts), eyes, nervous system (especially the brain), kidneys and genitals have been reported.

Effective contraception must be used by woman 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.

### **Driving and using machines**

PREGABANEURINE may produce dizziness, sleepiness and decreased concentration. 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.

**PREGABANEURINE contains lactose monohydrate**

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

**3. How to take PREGABANEURINE ?**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not take a larger dose than what was prescribed for you.

Your doctor will determine what dose is appropriate for you.

**Route of administration:** Oral route

**Peripheral and central neuropathic pain, epilepsy or Generalised Anxiety Disorder:**

- Take the number of capsules as instructed by your doctor.
- The dose, which has been adjusted for you and your condition, will generally be between 150 mg and 600 mg each day.
- Your doctor will tell you to take PREGABANEURINE either twice or three times a day. For twice a day take PREGABANEURINE once in the morning and once in the evening, at about the same time each day. For three times a day take PREGABANEURINE once in the morning, once in the afternoon and once in the evening, at about the same time each day.

If you have the impression that the effect of PREGABANEURINE is too strong or too weak, talk to your doctor or pharmacist.

If you are an elderly patient (over 65 years of age), you should take PREGABANEURINE normally except if you have problems with your kidneys.

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

Swallow the capsules whole with water.

Continue taking PREGABANEURINE until your doctor tells you to stop.

**If you take more PREGABANEURINE than you should**

Call your doctor or go to the nearest hospital emergency unit immediately. Take your box of PREGABANEURINE capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more PREGABANEURINE than you should. Fits have also been reported.

**If you forget to take PREGABANEURINE**

It is important to take PREGABANEURINE capsules regularly at the same time each day. If you forget a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

**If you stop taking PREGABANEURINE**

Do not stop taking PREGABANEURINE unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week.

After stopping long and short-term PREGABANEURINE treatment, you need to know that you may experience certain side effects. These include, trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, pain, sweating and dizziness. These symptoms may occur more commonly or severely if you have been taking PREGABANEURINE for a longer period of time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

##### **Very common: may affect more than 1 in 10 people**

- Dizziness, drowsiness, headache.

##### **Common: may affect up to 1 in 10 people**

- Increased appetite.
- Feeling of elation, confusion, disorientation, decrease in sexual interest, irritability.
- Disturbance in attention, clumsiness, memory impairment, loss of memory, tremor, difficulty with speaking, tingling feeling, numbness, sedation, lethargy, insomnia, fatigue, feeling abnormal.
- Blurred vision, double vision.
- Vertigo, problems with balance, fall.
- Dry mouth, constipation, vomiting, flatulence, diarrhoea, nausea, swollen abdomen.
- Difficulties with erection.
- Swelling of the body including extremities.
- Feeling drunk, abnormal style of walking.
- Weight gain.
- Muscle cramp, joint pain, back pain, pain in limb.
- Sore throat.

##### **Uncommon: may affect up to 1 in 100 people**

- Loss of appetite, weight loss, low blood sugar, high blood sugar.
- Change in perception of self, restlessness, depression, agitation mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attack, apathy, aggression, elevated mood, mental impairment, difficulty with thinking, increase in sexual interest, problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation.
- Changes in eyesight, unusual eye movement, changes in vision including tunnel vision flashes of light, jerky movements, reduced reflexes, increased activity, dizziness on standing, sensitive skin, loss of taste, burning sensation, tremor on movement, decreased consciousness, loss of consciousness, fainting, increased sensitivity to noise, feeling unwell.
- Dry eyes, eye swelling, eye pain, weak eyes, watery eyes, eye irritation.
- Heart rhythm disturbances, increased heart rate, low blood pressure, high blood pressure, high blood pressure, changes in heart beat, heart failure.
- Flushing, hot flushes.
- Difficulty breathing, dry nose, nasal congestion.
- Increased saliva production, heartburn, numb around mouth.
- Sweating, rash, chills, fever.
- Muscle twitching, joint swelling, muscle stiffness, pain including muscle pain, neck pain.
- Breast pain.
- Difficulty with or painful urination, incontinence.
- Weakness, thirst, chest tightness.
- Changes in blood and liver test results (blood creatinine phosphokinase increased, alanine aminotransferase increased, aspartate aminotransferase increased, platelet count decreased, neutropaenia, increase in blood creatinine, decrease in blood potassium).
- Hypersensitivity, swollen face, itchiness, hives, runny nose, nose bleed, cough, snoring.
- Painful menstrual periods.
- Coldness of hands and feet.

##### **Rare: may affect up to 1 in 1,000 people**

- Abnormal sense of smell, swinging vision, altered perception of depth, visual brightness, vision loss.
- Dilated pupils, cross eyes.
- Cold sweat, tightness of the throat, swollen tongue.
- Inflammation of the pancreas.
- Difficulty in swallowing.
- Slow or reduced movement of the body.
- Difficulty with writing properly.
- Increased fluid in the abdomen.
- Fluid in the lungs.
- Convulsions.
- Changes in the recording of electrical changes (ECG) in the heart which corresponds to heart rhythm disturbances.
- Muscle damage.
- Breast discharge, abnormal breast growth, breast growth in males.
- Interrupted menstrual periods.
- Kidney failure, reduced urine volume, urinary retention.
- Decrease in white blood cell count.
- Inappropriate behaviour, suicidal behavior, suicidal thoughts.
- Allergic reactions (which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction characterized by reddish, non-raised, target-shaped or circle-shaped spots on the trunk, often with central blisters, peeling skin, ulcers of the mouth, throat, nose, genitals and genital eyes. These severe rashes may be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis)).
- Jaundice (yellowing of the skin and eyes).
- parkinsonian syndrome, i.e. symptoms resembling those of Parkinson's disease; such as tremors, bradykinesia (decreased ability to move) and rigidity (muscle stiffness).

**Very rare: may affect up to 1 in 10,000 people**

- Liver failure
- Hepatitis (inflammation of the liver).
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**Not known: frequency cannot be estimated from the available data**

Become dependent on PREGABANEURINE (“medicine dependence”).

After stopping short or long term treatment with pregabaneurin you should be aware that you may experience certain side effects, called withdrawal effects (see “If you stop taking pregabaneurin”).

**If you experience swollen face or tongue or if your skin turns red and starts to blister or peel, you should seek immediate medical advice.**

Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to pregabalin and the severity of these effects may be increased when taken together.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine

## **5. How to store PREGABANEURINE ?**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What PREGABANEURINE contains**

- The active substance is pregabalin.

The other ingredients excipients are lactose monohydrate, talc, maize starch.

### **What PREGABANEURINE looks like and contents of the pack**

White capsule packaged in a box of 30 capsules in PVC/Aluminium blister.

**Category of distribution:** Prescription only medicines. LIST I

### **Marketing Authorisation Holder and Manufacturer**

#### ***Product license holder***

Exphar sa

Zoning Industriel de Nivelles Sud, zone II

Avenue Thomas Edison 105 - 1402 Thines

BELGIUM

#### ***Manufacturer***

Gracure Pharmaceuticals Ltd.,

E-1105, Industrial Area, Phase-III, Bhiwadi, Dist. Alwar (Raj.)

INDIA

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