Package leaflet: Information for the patient

Pregabalin SUN 50 mg capsules, Hard
Pregabalin SUN 75 mg capsules, Hard
Pregabalin SUN 100 mg capsules, Hard
Pregabalin SUN 150 mg capsules, Hard
Pregabalin SUN 225 mg capsules, Hard
Pregabalin SUN 300 mg capsules, Hard

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 Pregabalin SUN is and what it is used for

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

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

Generalised Anxiety Disorder:
Pregabalin SUN 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 Pregabalin SUN

Do not take Pregabalin SUN
- 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 Pregabalin SUN.
- Some patients taking pregabalin 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 using pregabalin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- Pregabalin 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.
- Pregabalin 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.
- 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.
- There have been reports of heart failure in some patients when taking pregabalin; 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 pregabalin. If while taking pregabalin you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.
- Some patients being treated with anti-epileptics such as pregabalin have had thoughts of harming or killing themselves or shown suicidal behaviour. If at any time you have these thoughts or shown such behaviour, immediately contact your doctor.
- When pregabalin is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g., constipation, blocked or paralysed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- Before taking this medicine, tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or illegal drugs; it may mean you have a greater risk of becoming dependent on pregabalin.
- There have been reports of convulsions when taking pregabalin or shortly after stopping pregabalin. If you experience a convulsion, contact your doctor immediately.
- There have been reports of reduction in brain function (encephalopathy) in some patients taking pregabalin when they have other conditions. Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease.
- There have been reports of breathing difficulties. If you have nervous system disorders, respiratory disorders, renal impairment, or you are older than 65, your doctor may prescribe you a different dosing regimen. Contact your doctor if you experience trouble breathing or shallow breaths.

Dependence
Some people may become dependent on pregabalin (a need to keep taking the medicine). They may have withdrawal effects when they stop using pregabalin (see section 3, “How to take Pregabalin SUN” and “If you stop taking Pregabalin SUN”).

If you have concerns that you may become dependent on pregabalin, it is important that you consult your doctor.

If you notice any of the following signs whilst taking Pregabalin SUN, it could be a sign that you have become dependent:

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to do this 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 Pregabalin SUN
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregabalin and certain other medicines may influence each other (interaction). When taken with certain other medicines which have sedative effects (including opioids), pregabalin may potentiate these effects, and could lead to respiratory failure, coma and death. The degree of dizziness, sleepiness and decreased concentration may be increased if pregabalin is taken together with medicines containing:

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

Pregabalin SUN may be taken with oral contraceptives.

Pregabalin SUN with food, drink and alcohol
Pregabalin SUN capsules may be taken with or without food.
It is advised not to drink alcohol while taking pregabalin.

Pregnancy, breast-feeding and fertility
Pregabalin SUN should not be taken during pregnancy or when breast-feeding, unless you are told otherwise by your doctor. Pregabalin use during the first 3 months of pregnancy may cause birth defects in the unborn child that require medical treatment. In a study reviewing data from women in Nordic countries who took pregabalin in the first 3 months of pregnancy, 6 babies in every 100 had such birth defects. This compares to 4 babies in every 100 born to women not treated with pregabalin in the study. Abnormalities of the face (orofacial clefts), the eyes, the nervous system (including the brain), kidneys and genitals have been reported.

Effective contraception must be used by women of childbearing 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
Pregabalin 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.

Pregabalin SUN contains sodium and mannitol
This medicine contains less than 1 mmol sodium (23 mg) per Hard capsule, that is to say essentially 'sodium-free'.

Mannitol may have a mild laxative effect.

3. How to take Pregabalin SUN

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not take more medicine than prescribed.

Your doctor will determine what dose is appropriate for you.

Pregabalin SUN is for oral use only.

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 Pregabalin SUN either twice or three times a day. For twice a day take Pregabalin SUN once in the morning and once in the evening, at about the same time each day. For three times a day take Pregabalin SUN 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 Pregabalin SUN 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 Pregabalin SUN 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 capsule whole with water.

Continue taking Pregabalin SUN until your doctor tells you to stop.

If you take more Pregabalin SUN than you should
Call your doctor or go to the nearest hospital emergency unit immediately. Take your box or bottle of Pregabalin SUN capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more pregabalin than you should. Fits and unconsciousness (coma) have also been reported.

If you forget to take Pregabalin SUN
It is important to take your Pregabalin SUN capsules regularly at the same time each day. If you forget to take 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 Pregabalin SUN
Do not suddenly stop taking Pregabalin SUN. If you want to stop taking pregabalin, discuss this with your doctor first. They will tell you how to do this.
If your treatment is stopped it should be done gradually over a minimum of 1 week.

After stopping a short or long-term treatment with pregabalin, you need to know that you may experience certain side effects, so-called withdrawal effects. These effects include trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness. These effects may occur more commonly or severely if you have been taking pregabalin for a longer period of time. If you experience withdrawal effects, you should contact your doctor.

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.

Serious side effects:

If any of the following happen, stop taking Pregabalin SUN and contact a doctor or go to the nearest hospital immediately, as you may need urgent medical attention.

- Hypersensitivity (uncommon, may affect up to 1 in 100 people) and allergic reactions (which may include swollen face, swollen tongue, difficulty breathing, itchiness) (rare, may affect up to 1 in 1,000 people).
- Serious skin reaction characterized by reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flulike symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis). (rare, may affect up to 1 in 1,000 people).
  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.
- Inflammation of the pancreas (which includes symptoms such as severe upper stomach pain, often with nausea and vomiting) (rare, may affect up to 1 in 1,000 people).

Other side effects:

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, spasm in neck
- 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 attacks, 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, abnormal uncontrolled movements of the limbs, 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, heart failure
- Flushing, hot flushes
- Difficulty breathing, dry nose, nasal congestion
- Cough, swollen face, hives, itchiness, runny nose, nose bleed, snoring
- Increased saliva production, heartburn, numb around mouth
- Sweating, rash, chills, fever
- Coldness of hands and feet
- Muscle twitching, joint swelling, muscle stiffness, pain including muscle pain, neck pain
- Difficulty with or painful urination, incontinence
- Weakness, thirst, chest tightness
- Breast pain
- Painful menstrual periods
- Generalised swelling
- Changes in blood and liver test results (blood creatinine phosphokinase increased, alanine amino transferase increased, aspartate aminotransferase increased, platelet count decreased, decrease in blood potassium, increase in blood creatinine, neutropenia).

Rare (may affect up to 1 in 1,000 people)
- Changes in heart beat
- Abnormal sense of smell, changes in vision including swinging vision, altered perception of depth, visual brightness, vision loss
- Dilated pupils, cross eyes
- Inflammation of the eyes (keratitis)
- Cold sweat, tightness of the throat, swollen tongue
- Difficulty in swallowing
- Slow or reduced movement of the body
- Difficulty with writing properly
- Fluid in the lungs
- Convulsions
- Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances
- Increased fluid in the abdomen
- 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 behaviour, suicidal thoughts
- Jaundice (yellowing of the skin and eyes)
- Parkinsonism, that is symptoms resembling Parkinson’s disease; such as tremor, bradykinesia (decreased ability to move), and rigidity (muscle stiffness).

Very rare (may affect up to 1 in 10,000 people)
- Liver failure

- Inflammation of the liver (hepatitis)

Not known: frequency cannot be estimated from the available data
- Becoming dependent on pregabalin ('drug dependence').

After stopping a short or long-term treatment with Pregabalin SUN, you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking Pregabalin SUN").

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.

The following adverse reaction has been reported in the post-marketing experience: Trouble breathing, shallow breaths.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pregabalin SUN

- 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 blister/bottle/carton. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions
- Bottle: Once the bottle is opened the capsules should be used within 30 days
- 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 Pregabalin SUN contains
The active substance is pregabalin.
Pregabalin SUN 50 mg: Each capsule, Hard contains 50 mg of pregabalin.
Pregabalin SUN 75 mg: Each capsule, Hard contains 75 mg of pregabalin.
Pregabalin SUN 100 mg: Each capsule, Hard contains 100 mg of pregabalin.
Pregabalin SUN 150 mg: Each capsule, Hard contains 150 mg of pregabalin.
Pregabalin SUN 225 mg: Each capsule, Hard contains 225 mg of pregabalin.
Pregabalin SUN 300 mg: Each capsule, Hard contains 300 mg of pregabalin.

The other excipients are:
Capsules content:
Mannitol, talc

Capsules shell:
Gelatin, titanium dioxide (E171), purified water, sodium lauryl sulphate.
Only for 75 mg, 100 mg, 225 mg and 300 mg, Iron oxide red (E172)

Printing Ink:
Shellac, propylene glycol, black iron oxide (E172), potassium hydroxide

What Pregabalin SUN looks like and contents of the pack

50 mg capsules: Hard gelatin capsules of size '2' with white opaque cap and white opaque body imprinted with black ink 'rbx' with band on cap and 'PG50' with band on body containing white to off white powder. The length of the capsule is approximately 17.0-18.2 mm.
75 mg capsules: Hard gelatin capsules of size '4' with red opaque cap and white opaque body imprinted with black ink 'rbx' on cap and 'PG75' on body containing white to off white powder. The length of the capsule is approximately 14.0-14.8 mm
100 mg capsules: Hard gelatin capsules of size '3' with red opaque cap and red opaque body imprinted with black ink 'rbx' on cap and 'PG100' on body containing white to off white powder. The length of the capsule is approximately 15.3-16.3 mm.
150 mg capsules: Hard gelatin capsules of size '2' with white opaque cap and white opaque body imprinted with black ink 'rbx' on cap and 'PG150' on body containing white to off white powder. The length of the capsule is approximately 17.0-18.2 mm.
225 mg capsules: Hard gelatin capsules of size '1' with red opaque cap and white opaque body imprinted with black ink 'rbx' on cap and 'PG225' on body containing white to off white powder. The length of the capsule is approximately 18.6-19.7 mm.
300 mg capsules: Hard gelatin capsules of size '0' with red opaque cap and white opaque body imprinted with black ink 'rbx' on cap and 'PG300' on body containing white to off white powder. The length of the capsule is approximately 21.0-21.8 mm.

OPA/Al/PVC//Al blister
For 50, 100, 150, 225 and 300 mg
Pack sizes: 14, 21, 56, 84, 98, 100 or 112 capsules, Hard

For 75 mg
Pack sizes: 14, 21, 56, 70, 84, 98, 100 or 112 capsules, Hard

PVC//Al blister
For 50, 100 and 225 mg:
Pack sizes: 14, 21, 56, 84, 98, 100 or 112 capsules, Hard.

For 75 mg
Pack sizes: 14, 21, 28, 56, 70, 84, 98, 100 or 112 capsules, Hard

For 150 and 300mg
Pack sizes: 14, 21, 28, 56, 84, 98, 100 or 112 capsules, Hard.

HDPE bottle with child resistance closure (PP)

For 50, 75, 100, 150, 225mg and 300 mg:
Pack sizes: 14, 21, 30, 56, 84, 98, 100 or 112 capsules, Hard

HDPE bottle with screw cap (PP)
Pack size: 500 capsules, Hard

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

France:	PREGABALINE CRISTERS PHARMA 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 300 mg gélule
Germany:	PREGABALIN BASICS 25 mg, 50 mg, 75 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 225 mg, 250 mg, 275 mg, 300 mg Hartkapseln
Poland:	Tabagine
Romania:	Pregabalină Terapia 75 mg, 125 mg, 150 mg, 175 mg, 250 mg, 275 mg, 300 mg capsule
Spain:	Pregabalina SUN 25 mg, 75 mg, 150 mg, 300 mg cápsulas duras EFG
The Netherlands:	Pregabaline SUN 75 mg, 150 mg, 300 mg Harde capsules
United Kingdom (Northern Ireland):	Pregabalin SUN 50 mg, 75 mg, 100 mg, 150 mg, 225 mg, 300 mg Capsules, Hard

This leaflet was last revised in February 2024.