Package Leaflet: Information For The User

Pregabalin Accord 25 mg hard capsules,
Pregabalin Accord 50 mg hard capsules,
Pregabalin Accord 75 mg hard capsules,
Pregabalin Accord 100 mg hard capsules,
Pregabalin Accord 150 mg hard capsules,
Pregabalin Accord 200 mg hard capsules,
Pregabalin Accord 225 mg hard capsules,
Pregabalin Accord 300 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 Pregabalin Accord is and what it is used for

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

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

Generalised Anxiety Disorder
This medicine 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 Accord

Do not take Pregabalin Accord
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 Accord.

- Some patients taking this medicine 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.

- This medicine 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.

- This medicine 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 this medicine; 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 this medicine. If while taking this medicine 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 Accord 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 Accord 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 you should 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 Accord.

- There have been reports of convulsions when taking this medicine or shortly after stopping this medicine. If you experience a convulsion, contact your doctor immediately.

- There have been reports of reduction in brain function (encephalopathy) in some patients taking this medicine 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.

Serious skin rashes including Stevens-Johnson syndrome, 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.

Dependence

Some people may become dependent on Pregabalin Accord (a need to keep taking the medicine). They may have withdrawal effects when they stop using Pregabalin Accord (see section 3, "How to take Pregabalin Accord" and "If you stop taking Pregabalin Accord"). If you have concerns that you may become dependent on Pregabalin Accord, it is important that you consult your doctor.

If you notice any of the following signs whilst taking Pregabalin Accord, 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 Accord
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregabalin Accord and certain other medicines may influence each other (interaction). When taken with certain other medicines which have sedative effects (including opioids), This medicine 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 Accord is taken together with medicines containing:

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

This medicine may be taken with oral contraceptives.

Pregabalin Accord with food, drink and alcohol
This medicine may be taken with or without food.

It is advised not to drink alcohol while taking this medicine.

Pregnancy and breast-feeding
This medicine 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 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
This medicine 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 Accord contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free'.

3. How to take Pregabalin Accord

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

Your doctor will determine what dose is appropriate for you.

This medicine 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 this medicine either twice or three times a day. For twice a day take this medicine once in the morning and once in the evening, at about the same time each day. For three times a day take this medicine 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 this medicine 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 this medicine 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 this medicine until your doctor tells you to stop.

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

If you forget to take Pregabalin Accord
It is important to take your medicine 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 Accord
Do not suddenly stop taking this medicine 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 Pregabalin Accord treatment, you need to know that you may experience certain side effects so-called withdrawal effects. These include, trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, pain, sweating, and dizziness. These effects may occur more commonly or severely if you have been taking this medicine 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.

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, 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 amino transferase increased, aspartate aminotransferase increased, platelet count decreased, neutropenia, 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 correspond 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 behaviour, suicidal thoughts.
- Allergic reactions which may include difficulty breathing, inflammation of the eyes (keratitis) and a 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 flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- 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.
- Hepatitis (inflammation of the liver).

Not known: frequency cannot be estimated from the available data

• Becoming dependent on Pregabalin Accord ('drug dependence').

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 (see "If you stop taking Pregabalin Accord").

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.

The following adverse reaction has been reported in the postmarketing 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pregabalin Accord

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 or bottle. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

HDPE bottle pack should be used within 30 days (for 30's count) and 100 days (for 200's count) after first opening.

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 Accord contains

The active substance is pregabalin. Each hard capsule contains either 25 mg**,** 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, 300 mg of pregabalin.

The other ingredients are: starch pregelatinise, talc (E553b), gelatin, titanium dioxide (E171), sodium laurilsulfate, black ink, (which contains shellac, propylene glycol, iron oxide black (E172), and, potassium hydroxide).

The 75 mg, 100 mg, 200 mg, 225 mg and 300 mg capsules also contain iron oxide red (E172).

What Pregabalin Accord looks like and contents of the pack	
25 mg capsules	White opaque/White opaque, size "4" hard gelatin capsules, imprinted with 'PG' on cap and '25' on body. Each capsule is approximately 14.4 mm in length.
50 mg capsules	White opaque/White opaque, size "3" hard gelatin capsules, imprinted with 'PG' on cap and '50' on body. Each capsule is approximately 15.8 mm in length.
75 mg capsules	Red opaque/White opaque, size "4" hard gelatin capsules, imprinted with 'PG' on cap and '75' on body. Each capsule is approximately 14.4 mm in length.
100 mg capsules	Red opaque/Red opaque, size "3" hard gelatin capsules, imprinted with 'PG' on cap and '100' on body. Each capsule is approximately 15.8 mm in length.
150 mg capsules	White opaque/White opaque, size "2" hard gelatin capsules, imprinted with 'PG' on cap and '150' on body. Each capsule is approximately 17.8 mm in length.
200 mg capsules	Orange opaque/Orange opaque, size "1" hard gelatin capsules, imprinted with 'PG' on cap and '200' on body. Each capsule is approximately 19.3 mm in length.
225 mg capsules	Orange opaque/White opaque, size "1" hard gelatin capsules, imprinted with 'PG' on cap and '225' on body. Each capsule is approximately 19.3 mm in length.
300 mg capsules	Red opaque/White opaque, size "0" hard gelatin capsules, imprinted with 'PG' on cap and '300' on body. Each capsule is approximately 21.4 mm in length.

Pregabalin Accord 25/50/75/100/150/200/225/300mg hard capsules are available in blister packs (PVC/Aluminium) containing 14, 21, 56, 60, 84, 90, 100 or 112 hard capsules. Additionally Pregabalin Accord 75mg hard capsules are also available in PVC/Aluminium blisterin pack sizes of 70 hard capsules.

Pregabalin Accord 25/50/75/100/150/200/225/300mg hard capsules are available in 100 x 1 hard capsules in PVC/Aluminium perforated unit dose blisters.

Pregabalin Accord 25/50/75/100/150/200/225/300mg hard capsules are also available in an HDPE bottle containing 30 or 200 hard capsules.

Not all pack sizes may be marketed.

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This leaflet was approved in January 2023.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu