**Package leaflet: Information for the user**

**Brieka 25 mg Hard Capsules**
**Brieka 50 mg Hard Capsules**
**Brieka 75 mg Hard Capsules**
**Brieka 100 mg Hard Capsules**
**Brieka 150 mg Hard Capsules**
**Brieka 200 mg Hard Capsules**
**Brieka 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 Brieka is and what it is used for

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

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

**Generalised Anxiety Disorder:** Brieka 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 Brieka

**Do not take Brieka**
- 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 Brieka

- Some patients taking Brieka 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.

- Brieka 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.

- Brieka 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 Brieka; 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 Brieka. If while taking Brieka 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 Brieka have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

- When Brieka 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 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 Brieka or shortly after stopping Brieka. If you experience a convulsion, contact your doctor immediately.

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

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

Brieka and certain other medicines may influence each other (interaction). When taken with certain other medicines, Brieka 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 Brieka is taken together with medicinal products containing:

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

Brieka may be taken with oral contraceptives.

**Brieka with food, drink and alcohol**
Brieka capsules may be taken with or without food.

It is advised not to drink alcohol while taking Brieka.

**Pregnancy and breast-feeding**
Brieka 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.

**Driving and using machines**
Brieka 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.

## 3. How to take Brieka

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.

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

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

**If you forget to take Brieka**
It is important to take your Brieka 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 Brieka**
Do not stop taking Brieka 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 Brieka 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 Brieka 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.

**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.**

**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, 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 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.
- Allergic reactions (which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction characterized by rash, blisters, peeling skin and pain).
- Jaundice (yellowing of the skin and eyes).

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

- Liver failure.
- Hepatitis (inflammation of the liver).

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Brieka

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, blister or bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Brieka contains**

- The active substance is pregabalin. Each hard capsule contains either 25 mg**,** 50 mg, 75 mg, 100 mg, 150 mg, 200 mg or 300 mg pregabalin.
- The other ingredients are: mannitol, Co-processed starch (pregelatinised starch and maize starch), talc, gelatine, titanium dioxide (E171) and black ink, (which contains shellac, black iron

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

**What Brieka looks like and contents of the pack**

| | |
|---|---|
| 25 mg capsules | White Hard Capsules (14.5 mm), with “PGB 25” marked on the body. |
| 50 mg capsules | White Hard Capsules (16 mm), with “PGB 50” marked on the body. The capsule body is marked with a black band. |
| 75 mg capsules | White and orange Hard Capsules (14.5 mm), with “PGB 75” marked on the body. |
| 100 mg capsules | Orange Hard Capsules (16 mm), with “PGB 100” marked on the body. |
| 150 mg capsules | White Hard Capsules (18 mm), with “PGB 150” marked on the body. |
| 200 mg capsules | Light orange Hard Capsules (19.5 mm), with “PGB 200” marked on the body. |
| 300 mg capsules | White and orange Hard Capsules (21.5 mm), with “PGB 300” marked on the body. |

Brieka 25 mg, 50 mg, 75 mg, 100 mg and 200 mg is available in eight pack sizes made of PVC with an aluminium foil backing: 14, 21, 30, 56, 60, 84, 90 and 100 capsules.
Brieka 150 mg is available in five pack sizes made of PVC with an aluminium foil backing: 14, 30, 56, 60 and 100 capsules.
Brieka 300 mg is available in four pack sizes made of PVC with an aluminium foil backing: 14, 56, 60 and 100 capsules.

In addition, Brieka is available in a plastic bottle containing 100 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

*Marketing Authorisation Holder*
Accord Healthcare Ireland Ltd, Euro House, Euro Business Park, Little Island, Cork T45 K857, Ireland

*Manufacturer*
Balkanpharma-Dupnitsa AD, 3 Samokovsko Str., Dupnitsa 2600, Bulgaria

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