

BRIEKA CAPSULES

Pregabalin (50mg, 75mg, 150mg)

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What Brieka is used for

Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.

Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

Pregabalin is indicated for the management of fibromyalgia.

How Brieka works

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

Before you use Brieka

-When you must not take it

Do not start taking if you are allergic to pregabalin or any of the ingredients in Brieka.

Symptoms of an allergic reaction to pregabalin may include swelling of the face, lips, tongue, and throat, shortness of breath, wheezing as well as skin rashes.

-Before you start to take it

Talk to your doctor or pharmacist before you take Brieka:

- have or had depression, mood problems or suicidal thoughts or behaviour
- have kidney problems or get kidney dialysis
- have heart problems including heart failure

- have a bleeding problem or a low blood platelet count

- have abused prescription medicines, street drugs, or alcohol in the past

- have ever had swellings in your face, mouth, tongue, lips, gums, neck or throat (angioedema)

- have eye problems. 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.

- are pregnant or plan to become pregnant. It is not known if pregabalin will harm your unborn baby. You and your doctor will have to decide if you should take pregabalin while you are pregnant.

- pregabalin passes into breast milk and should not be taken while breastfeeding.

-Taking other medicines

Only take other medicines while you are on Brieka if your doctor tells you that you can.

When taken with certain other medicines, Brieka may potentiate the side effects seen with these medicines, including respiratory failure and coma, such as:

- other central nervous system (CNS) depressant medicinal products

The degree of dizziness, sleepiness and decreased concentration may be increased if Brieka is taken together with medicines containing:

- Oxycodone; used as a pain-killer

- Lorazepam; used for treating anxiety

- Alcohol

Know the medicines you take.

Keep a list of them with you to show your doctor and pharmacist each time you get a new medicine. Do not start a new medicine without talking with your doctor.

How to take Brieka

-How much to take

Take Brieka exactly as prescribed. Your doctor will tell you how much to take.

- Brieka may be taken with or without food.

- Your doctor may change your dose. Do not change your dose without talking to your doctor.

-When to take it

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

-How long to take it

Always take this medicine exactly as your doctor has told you.

If you stop taking Brieka suddenly you may have headaches, nausea, diarrhoea or trouble sleeping. If you have epilepsy and you stop taking Brieka suddenly, you may have seizures more often.

Talk with your doctor about how to stop Brieka slowly.

-If you forget to take it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. Do not take two doses at the same time.

-If you take too much (overdose)

If you take too much Brieka, call your doctor or go to the nearest emergency room right away.

Symptoms of overdosage include:

mood disorder such as depression, confusional state, agitation, somnolence, and restlessness.

While you are using Brieka

-Things you must do

Stop taking Brieka and call your doctor immediately if you have any of these signs of a serious allergic reaction:

- Swelling of your face, mouth,

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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

-Things you must not do

Do not drive a car, work with machines, or do other dangerous activities until you know how Brieka affects you.

Ask your doctor about when it will be okay to do these activities.

-Things to be careful of

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

- Stopping Brieka 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.

Pay attention to any changes, especially sudden changes, in mood, behaviours, thoughts or feelings. Keep all follow-up visits with your doctor as scheduled. Call your doctor between visits as needed, especially if you are worried about symptoms.

Side Effects

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

The side effects include:

Very common:

- dizziness
- drowsiness
- headache

Common:

- inflammation of the upper pharynx
- 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)
- 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.

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Brieka

-Storage

Store below 30°C.

-Disposal

Do not use after the expiry date stated on the label.

Take any unused capsules back to your pharmacist to be destroyed. Only keep the capsules if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

Product Description

-What it looks like

50mg: White cap and white body, hard gelatine capsules size 3. Markings on body: "PGB 50" with a black band.

75mg: Orange cap and white body, hard gelatine capsules size 4. Markings on body: "PGB 75".

150mg: White cap and white body, hard gelatine capsules size 2. Markings on body: "PGB 150".

-Ingredients

Active Ingredient

50mg: Each capsule contains 50mg pregabalin

75mg: Each capsule contains 75mg pregabalin

150mg: Each capsule contains 150mg pregabalin

Inactive ingredients

Mannitol, corn starch, pregelatinised corn starch, talc.

Hard capsules

75mg: consist of titanium dioxide, gelatin, iron oxide red, water

50mg and 150mg: consist of titanium dioxide, gelatin, water

-MAL number

Brieka capsules 50mg:
MAL18066054AZ

Brieka capsules 75mg:
MAL18046172AZ

Brieka capsules 150mg:
MAL18046171AZ

Manufacturer

Balkanpharma-Dupnitsa AD
3 Samokovsko Shosse Str.,
Dupnitsa 2600, Bulgaria

Product Registration Holder

DCH Auriga (Malaysia) Sdn. Bhd.
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