Gabapentin 100 mg capsules, hard
Gabapentin 300 mg capsules, hard
Gabapentin 400 mg capsules, hard

gabapentin

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

In this leaflet:
1. What Gabapentin capsules are and what they are used for
2. What you need to know before you take Gabapentin capsules
3. How to take Gabapentin capsules
4. Possible side effects
5. How to store Gabapentin capsules
6. Contents of the pack and other information

1. WHAT GABAPENTIN CAPSULES ARE AND WHAT THEY ARE USED FOR

Gabapentin capsules, hard (polished Gabapentin capsules in the rest of this leaflet) belong to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

Gabapentin capsules are used to treat:
- Gabapentin capsules are used to treat:
  - Neuropathic pain (long lasting pain caused by damage to the nerves).
  - A variety of different diseases can cause neuropathic pain (principally occurring in the legs and/or arms), such as diabetes or shingles. Pain sensations may be described as hot, burning, trembling, shooting, stabbing, sharp, cramplike, aching, tingling, numbness, paresthesia and pain in the hands and feet.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GABAPENTIN CAPSULES

Do not take Gabapentin capsules:
- If you are allergic (hypersensitive) to gabapentin or any of the other ingredients of Gabapentin capsules (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Gabapentin capsules:
- If you suffer from kidney problems your doctor may prescribe a different dosing schedule.
- If you have recently taken heroin or other opioids (or had problems with them), Gabapentin capsules can be used to treat your recurring pain if you were also taking opioids.

In addition, Gabapentin capsules can be used to:
- Treat alcohol or dependence has been reported for gabapentin from the post-marketing experience. Talk to your doctor if you have a history of alcohol or dependence. A small number of people being treated with antiepileptic such as gabapentin have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Important information about potentially serious reactions

A small number of people taking Gabapentin capsules get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. You need to know these symptoms by looking out for while you are taking Gabapentin capsules.

Read the description of these symptoms in section 4 of this leaflet under ‘Contact your doctor immediately if you experience any of the following symptoms after taking this medication as they can be serious’.

Other medicines and Gabapentin capsules - Please tell your doctor or pharmacist if you are taking or have taken recently any other medicines, including medicines obtained without a prescription. In particular, tell your doctor (or pharmacist) if you are taking or have been taking any medicines for conditions such as depression, anxiety, or any other neurological or psychiatric problems.

Medications containing opioid salts or morphine - If you are taking any medicines containing opioids (such as morphine), please tell your doctor or pharmacist as opioids may increase the effect of Gabapentin capsules.

In addition, Gabapentin capsules with or without added caffeine and Gabapentin capsules with or without added aspirin should not be taken at the same time.

Gabapentin capsules are not a substitute for alcohol or your doctor, hospital or pharmacist how you are taking.

Gabapentin capsules are not suitable for use with alcohol or with medicines that contain alcohol.

Gabapentin capsules with food - Gabapentin capsules can be taken:
- with or without food.

Pregnancy, breast-feeding and fertility

Pregnancy - Gabapentin capsules should not be taken during pregnancy, unless you are already taking them to treat seizures. Effectiveness contraconception must be used by women of childbearing potential not treated with Gabapentin capsules and women who have previously been treated with Gabapentin capsules who may subsequently become pregnant. Counseling on contraceptive use should be provided as soon as the need for it is known.

Breast-feeding - Gabapentin, the active substance of Gabapentin capsules, is passed on

Thru breast milk. Because the effect on the baby is unknown, it is not recommended to breast feed while using Gabapentin capsules.

Ask your doctor or pharmacist for advice before taking any medicine.

Fertility - There is no effect on fertility in animal studies.

Driving and using machines - Gabapentin capsules may produce dizziness, drowsiness and tiredness. You should not drive, operate complex machinery or take part in other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

Gabapentin capsules contain lactose - Gabapentin capsules contain lactose (a type of sugar). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking the medicinal product.

3. HOW TO TAKE GABAPENTIN CAPSULES

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will determine what dose is appropriate for you. If you have the impression that the effect of Gabapentin capsules is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

If you are an elderly patient (over 65 years of age), you should take the normal dose of Gabapentin capsules unless you have problems with your kidney. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

Continue taking Gabapentin capsules until your doctor tells you to stop.

Method and route of administration

Gabapentin capsules are for oral use. Always swallow the capsules whole with plenty of water.

Epilepsy, the recommended dose is:

Adults and adolescents: Take the number of capsules as instructed. Your doctor will usually start you on 3 capsules each day. The starting dose will generally be between 300 mg and 600 mg each day. Thereafter, the dose can be increased by your doctor up to a maximum of 3600 mg each day. You must take Gabapentin capsules at a fixed time each day, i.e. in the morning, in the afternoon and in the evening.

Children aged 9 years and above: The dose will be given to your child, and it is essential that your doctor is suitably calculated against your child’s weight. The treatment is started with a low initial dose which is gradually increased over a period of approximately 3 days. The usual dose to control epilepsy is 25-35 mg/kg body weight per day. It is usually given 3 separate doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.
Gabapentin capsules are not recommended for use in children below 6 years of age.

Peripheral Neuropathic Pain, the recommended dose in adults:

Take the number of capsules as instructed by your doctor. Your doctor will usually build your dose gradually. The starting dose of gabapentin will generally be between 200 mg and 400 mg each day. Subsequently, this dose may be increased by your doctor, up to a maximum of 3600 mg each day, and your doctor will tell you to take this in 3 separate doses, i.e., once in the morning, once in the afternoon and once in the evening.

If you have kidney problems or are receiving haemodialysis:

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

If you take more gabapentin capsules than you should: If you or someone else accidentally takes too many capsules, if you think that you have swallowed any, contact your doctor or go to your nearest hospital casualty department immediately. Take along any capsules that you have not taken together with the container and the label so that the hospital can easily tell what medicine you have taken. An gabapentin capsule may make you drowsy; it is recommended that you do not drive or operate machinery else you decide to do so. There are also severe cases of acute pancreatitis (an inflamed pancreas).

Gabapentin capsules may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your nose or blood cells. You may or may not have rash when you get this type of reaction. It may cause you to be hospitalised or stop Gabapentin capsules. Call your doctor night away if you have any of the following symptoms:

- severe nausea
- fever
- liver function tests
- frequent infection
- breathing problems, which if severe you need emergency and intensive care to continue breathing normally.

These symptoms may be the first signs of a serious reaction. A doctor should examine you to decide if you should continue taking Gabapentin capsules.

If you are on blood-thinners, tell your doctor if you develop muscle pain or weakness.

Other side effects include:

Common (which may affect more than 1 person in 10):

- Infections
- Feeling sleepy, dizziness, lack of coordination
- Feeling tired
- Common (which may affect more than 1 person in 100):

- Pneumonia, respiratory infections, urinary tract infection, inflammation of the ear or other infections
- Low white blood cell counts
- Anorexia, increased appetite
- Anger towards others, confusion, mood changes, depression, anxiety, nervousness, difficulty with sleeping
- Constipation, pain, vomiting
- Decreased appetite
- Weakness or tiredness
- Increased thirst
- Skin rash, which may be severe
- Insomnia
- Acute pancreatitis
- Blurred vision, double vision
- Gastrointestinal symptoms
- Acute pancreatitis
- Low blood counts
- Low blood pressure
- Nausea
- Increased appetite
- Constipation
- Increased thirst
- Anorexia
- Acute pancreatitis
- Fifteen percent of patients with diabetes: Diabetes (most often observed in patients with diabetes) - Ketones in state of chronic malnutrition and uncontrolled and uncontrolled diabetes

Rare (may affect less than 1 person in 1000):

- Allergic reactions such as hives
- Decreased movement - Racing heartbeat - Severe rash that may involve the face, trunk and limbs - Altered blood test results suggesting problems with the liver - Mental impairment - Fall
- Difficulty with thinking - High blood sugar (most often observed in patients with diabetes) - Ketones in state of chronic malnutrition and uncontrolled and uncontrolled diabetes

If any of the side effects become worse or you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or-name. 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 NHR A Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of the medicine.

5. HOW TO STORE GABAPENTIN CAPSULES

Keep out of the sight and reach of children. Do not use Gabapentin capsules after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. Do not store Gabapentin capsules above 30°C. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Gabapentin capsules contain:

The active substance is gabapentin. Each hard capsule contains either 100 mg, 200 mg or 400 mg gabapentin. The other ingredients in Gabapentin capsules are: Capsule contents: Lactose monohydrate, magnesium stearate and talc. Capsule shell: gelatin. The 100 mg capsules contain the colouring E111 (Titanium dioxide); the 200 mg capsules contain the colourings: E131 (Titanium dioxide) and E102 (sunset yellow); the 400 mg capsules contain the colourings: E111 (Titanium dioxide) and E114 (red iron oxide). The printing ink used on all capsules contains shellac, iron oxide black E172.

What Gabapentin capsules look like and contents of the pack:

The 100 mg capsules are white hard gelatin capsules marked with “100”. The 200 mg capsules are yellow hard gelatin capsules marked with “200”. The 400 mg capsules are orange hard gelatin capsules marked with “400”. Supplied in PVC/Aluminium foil blister packs of 100 capsules.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation holder: RURIS PHARM UK Ltd.

Manufacturer: Laboratories BTT

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