

Gabapentina Gabamox 100 mg hard capsules **Gabapentina Gabamox 300 mg hard capsules** **Gabapentina Gabamox 400 mg hard capsules**

Gabapentina

Read this entire leaflet carefully before you start taking this medicine.

- 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.

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1. What Gabapentina Gabamox is and what it is used for
2. Before you take Gabapentina Gabamox
3. How to take Gabapentina Gabamox
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1. WHAT GABAPENTINA GABAMOX IS AND WHAT IT IS USED FOR

Gabapentina Gabamox belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain.

Epilepsy: Gabapentina Gabamox is used to treat various forms of epilepsy (seizures that are initially limited to certain parts of the brain, whether the seizure spreads to other parts of the brain or not). Your doctor will prescribe Gabapentina Gabamox for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Gabapentina Gabamox in addition to your current treatment unless told otherwise. Gabapentina Gabamox can also be used on its own to treat adults and children over 12 years of age.

Peripheral neuropathic pain: Gabapentina Gabamox is used to treat long lasting pain caused by damage to the nerves. A variety of different diseases can cause peripheral (primarily occurring in the legs and/or arms) 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 etc.

2. BEFORE YOU TAKE GABAPENTINA GABAMOX

Do not take Gabapentina Gabamox

If you are allergic (hypersensitive) to Gabapentina or any of the other ingredients of Gabapentina Gabamox.

Take special care with Gabapentina Gabamox

- if you suffer from kidney problems
- if you develop signs such as persistent stomach pain, feeling sick and being sick contact your doctor immediately.
- A small number of people being treated with anti-epileptics such as Gabapentina have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking any medicines containing morphine, please tell your doctor or pharmacist as morphine may increase the effect of Gabapentina Gabamox.

Gabapentina Gabamox is not expected to interact with other antiepileptic drugs or the oral contraceptive pill.

Gabapentina Gabamox may interfere with some laboratory tests, if you require a urine test tell your doctor or hospital that you are taking Gabapentina Gabamox.

If Gabapentina Gabamox and antacids containing aluminium and magnesium are taken at the same time, absorption of Gabapentina Gabamox from the stomach may be reduced. It is therefore recommended that Gabapentina Gabamox is taken at the earliest two hours after taking an antacid.

Taking Gabapentina Gabamox with food and drink

Gabapentina Gabamox can be taken with or without food.

Pregnancy and breast-feeding

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

Gabapentina Gabamox should not be taken during pregnancy, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential.

There have been no studies specifically looking at the use of Gabapentina in pregnant women, but other medications used to treat seizures have reported an increased risk of harm to the fetus, particularly when more than one seizure medication is taken at the same time. Therefore, whenever possible and only under the advice of your doctor, you should try to take only one seizure medication during pregnancy.

Do not suddenly discontinue taking this medicine as this may lead to breakthrough seizure, which could have serious consequences for you and your baby.

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Gabapentina Gabamox.

Gabapentina, the active substance of Gabapentina Gabamox, is excreted in human milk. Because the effect on the nursing infant is unknown, it is not recommended to breast-feed your baby while using Gabapentina Gabamox.

Driving and using machines

Gabapentina Gabamox may produce dizziness, drowsiness and tiredness. You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether this medication affects your ability to perform these activities.

Important information about some of the ingredients of Gabapentina Gabamox

The capsules contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE GABAPENTINA GABAMOX

Always take Gabapentina Gabamox 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 Gabapentina Gabamox 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 Gabapentina Gabamox 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.

Always swallow the capsules whole with plenty of water.

Continue taking Gabapentina Gabamox until your doctor tells you to stop.

Peripheral Neuropathic Pain:

Take the number of capsules or tablets as instructed by your doctor. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 900 mg each day.

Thereafter, the dose may be increased stepwise up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening.

Epilepsy:

Adults and adolescents:

Take the number of capsules or tablets as instructed. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased stepwise up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening.

Children aged 6 years and above:

The dose to be given to your child will be decided by your doctor as it is 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/day. It is usually given in 3 divided doses, by taking the capsule(s) or tablet(s) each day, usually once in the morning, once in the afternoon and once in the evening.

Gabapentina Gabamox is not recommended for use in children below 6 years of age.

If you take more Gabapentina Gabamox than you should

Call your doctor or go to the nearest hospital emergency unit immediately. Take along any capsules or tablets that are left, the container and the label so that the hospital can easily tell what medicine you have taken.

If you forget to take Gabapentina Gabamox

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Gabapentina Gabamox

Do not stop taking Gabapentina Gabamox unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week. If you stop taking Gabapentina Gabamox suddenly or before your doctor tells you, there is an increased risk of seizures.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Very common side-effects which may affect more than 1 person in 10 are listed below:

- Viral infection
- Feeling drowsy, dizziness, lack of coordination
- Feeling tired, fever

Common side-effects which may affect more than 1 person in 100 are listed below:

- Pneumonia, respiratory infection, urinary tract infection, infection, inflammation of the ear
- Low white blood cell counts
- Anorexia, increased appetite
- Anger towards others, confusion, fluctuation in mood, depression, anxiety, nervousness, difficulty with thinking
- Convulsions, jerky movements, difficulty with speaking, loss of memory, tremor, difficulty sleeping, headache, sensitive skin, decreased sensation, difficulty with coordination, unusual eye movement, increased, decreased or absent reflexes
- Blurred vision, double vision
- Vertigo
- High blood pressure, flushing or dilation of blood vessels
- Difficulty breathing, bronchitis, sore throat, cough, dry nose
- Vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
- Facial swelling, bruises, rash, itch, acne
- Joint pain, muscle pain, back pain, twitching
- Incontinence
- Difficulties with erection
- Swelling in the legs and arms or swelling that may involve the face, trunk and limbs, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
- Decrease in white blood cells, increase in weight
- Accidental injury, fracture, abrasion

Rare side-effects which may affect less than 1 person in 1000 are listed below:

- Decreased platelets (blood clotting cells)
- Allergic reaction such as hives
- Hallucinations
- Problems with abnormal movements such as writhing, jerking movements and stiffness
- Ringing in the ears
- Racing heartbeat
- Inflammation of the pancreas
- Inflammation of the liver, yellowing of the skin and eyes
- Severe skin reactions that require immediate medical attention, swelling of the lips and face, skin rash and redness, hair loss
- Acute kidney failure
- Adverse events following the abrupt discontinuation of Gabapentina (anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
- Blood glucose fluctuations in patients with diabetes, abnormal blood test results suggesting problems with the liver.

Additionally in clinical studies in children, aggressive behaviour and jerky movements were reported commonly.

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.

5. HOW TO STORE GABAPENTINA GABAMOX

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package.

Do not use Gabapentina Gabamox after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 Gabapentina Gabamox contains

The active substance is Gabapentina. Each capsule, hard contains 100 mg, 300 mg or 400 mg Gabapentina.

Each capsule contains the following excipients:

Lactose monohydrate
Maize starch
Talc

The 100 mg capsule shell (n°3, light green and ivory) contains:

Cap:
Indigo carmine (E132) – DC&C blue 2
Quinoleine yellow (E104)
Titanium dioxide (E171)
Gelatin
Body
Yellow iron oxide (E172)
Titanium dioxide (E171)
Gelatin

The 300 mg capsule shell (n°0, dark green and white) contains:

Cap:
Indigo carmine (E132) – DC&C blue 2
Titanium dioxide (E171)
Yellow iron oxide (E172)
Gelatin
Body
Titanium dioxide (E171))
Gelatin

The 400 mg capsule shell (n°0, green and white) contains:

Cap:
Indigo carmine (E132) – DC&C blue 2
Titanium dioxide (E171)
Yellow iron oxide (E172)
Gelatin
Body
Titanium dioxide (E171))
Gelatin

What Gabapentina Gabamox looks like and contents of the pack

Capsule, hard

Gabapentina Gabamox is package in blister PVC+PVD/Al.

The available pack sizes are 20 or 60 capsules dosed at 100 mg and 60 capsules dosed at 300 mg or 400 mg. Not all pack sizes may be marketed.

Marketing Authorization Holder

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