

Package leaflet: Information for the user

Gabapentine Glenmark 100 mg harde capsules
Gabapentine Glenmark 300 mg harde capsules
Gabapentine Glenmark 400 mg harde capsules

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 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 [Name to be completed nationally] are and what they are used for
2. What you need to know before you take [Name to be completed nationally]
3. How to take [Name to be completed nationally]
4. Possible side effects
5. How to store [Name to be completed nationally]
6. Contents of the pack and other information

1. What X are and what they are used for

[Name to be completed nationally] belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (**long lasting pain caused by damage to the nerves**).

The active substance in [Name to be completed nationally] is gabapentin.

[Name to be completed nationally] are 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). The doctor treating you or your child 6 years of age and older will prescribe [Name to be completed nationally] to help treat epilepsy when the current treatment is not fully controlling the condition. You or your child 6 years of age and older should take [Name to be completed nationally] in addition to the current treatment unless told otherwise. [Name to be completed nationally] can also be used on its own to treat adults and children over 12 years of age.
- Peripheral neuropathic pain (**long lasting pain caused by damage to the nerves**). A variety of different diseases can cause peripheral neuropathic pain (primarily occurring in the legs and/or arms), 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. What you need to know before you take X

Do not take X:

- if you are **allergic** (hypersensitive) to gabapentin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking [Name to be completed nationally]:

- if you suffer from **kidney problems** your doctor may prescribe a different dosing schedule
- if you are on haemodialysis (to remove waste products because of **kidney failure**), tell your doctor if you develop muscle pain and/or weakness
- if you develop signs such as **persistent stomach pain**, feeling sick and being sick contact your doctor immediately as these may be symptoms of acute pancreatitis (an inflamed pancreas)
- if you have nervous system disorders, respiratory disorders, or you are more than 65 years old, your doctor may prescribe you a different dosing regimen
- Before taking this medicine, 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 [Name to be completed nationally]

Cases of abuse and dependence have been reported for gabapentin from the post-marketing experience. Talk to your doctor if you have a history of abuse or dependence.

A small number of people being treated with anti-epileptics such as gabapentin have had thoughts of **harming or killing themselves**. If at any time you have these thoughts, immediately contact your doctor.

Dependence

Some people may become dependent on [Name to be completed nationally] (a need to keep taking the medicine).

They may have withdrawal effects when they stop using [Name to be completed nationally] (see section 3, “How to take [Name to be completed nationally]” and “If you stop taking [Name to be completed nationally]”). If you have concerns that you may become dependent on [Name to be completed nationally], it is important that you consult your doctor.

If you notice any of the following signs whilst taking [Name to be completed nationally], it could be a sign that you have become dependent.

- You feel 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.

Important information about potentially serious reactions

Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with gabapentin. Stop using gabapentin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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 medicine as they can be serious*’

Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown which can be life-threatening

and lead to kidney problems. You may also experience **discoloration of your urine**, and a change in blood test results (notably blood creatine phosphokinase increased). If you experience any of these signs or symptoms, please contact your doctor immediately.

Other medicines and [Name to be completed nationally]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor (or pharmacist) if you are taking or have been recently taking any medicines for convulsions, sleeping disorders, depression, anxiety, or any other neurological or psychiatric problems.

Medicines containing opioids such as 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 [Name to be completed nationally]. In addition, combination of [Name to be completed nationally] with opioids may cause **sleepiness, sedation, decrease in breathing, or death**.

Antacids for indigestion

If [Name to be completed nationally] and antacids containing aluminium and magnesium are taken at the same time, absorption of [Name to be completed nationally] from the stomach may be reduced. It is therefore recommended that [Name to be completed nationally] are taken at the earliest **two hours after taking an antacid**.

[Name to be completed nationally]:

- is not expected to interact with other **antiepileptic drugs** or the **oral contraceptive pill**.
- may interfere with some laboratory tests, if you require a **urine** test tell your doctor or hospital what you are taking.

[Name to be completed nationally] with food

[Name to be completed nationally] can be taken with or without food.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

[Name to be completed nationally] 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 gabapentin in pregnant women, but other medications used to treat seizures have reported an increased risk of harm to the developing baby, particularly when more than one seizure medication is taken at the same time. Therefore, whenever possible, you should try to take only one seizure medication during pregnancy and only under the advice of your doctor.

If used during pregnancy, gabapentin may lead to withdrawal symptoms in newborn infants. This risk might be increased when gabapentin is taken together with opioid analgesics (drugs for treatment of severe pain).

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking [Name to be completed nationally]. Do not suddenly discontinue taking this medicine as this may lead to a breakthrough seizure, which could have serious consequences for you and your baby.

Breast-feeding

Gabapentin, the active substance of [Name to be completed nationally], is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using [Name to be completed nationally].

Fertility

There is no effect on fertility in animal studies.

Driving and using machines

[Name to be completed nationally] 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 medication affects your ability to perform these activities.

[Name to be completed nationally] contains lactose

[Name to be completed nationally] hard capsules contain lactose (a type of sugar). 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 [Name to be completed nationally]

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

Your doctor will determine what dose is appropriate for you.

Epilepsy, the recommended dose is

Adults and adolescents:

Take the number of capsules 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 as instructed 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.

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 per kg per day. It is usually given in 3 separate doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.

[Name to be completed nationally] is not recommended for use in children below 6 years of age.

Peripheral Neuropathic Pain, the recommended dose is

Adults

Take the number of capsules 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 as instructed 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 dose if you have problems with your kidneys or are undergoing haemodialysis.

If you are an elderly patient (over 65 years of age),

you should take the normal dose of [Name to be completed nationally] unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

If you have the impression that the effect of [Name to be completed nationally] is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Method of administration

[Name to be completed nationally] are for oral use. Always swallow the capsules with plenty of water.

Continue taking [Name to be completed nationally] until your doctor tells you to stop.

If you take more [Name to be completed nationally] than you should

Higher than recommended doses may result in an increase in side effects including loss of consciousness, dizziness, double vision, slurred speech, drowsiness and diarrhoea. Call your doctor or go to the nearest hospital emergency unit immediately if you take more [Name to be completed nationally] than your doctor prescribed. 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.

If you forget to take [Name to be completed nationally]

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 [Name to be completed nationally]

Do not suddenly stop taking [Name to be completed nationally]. If you want to stop taking [Name to be completed nationally], discuss this with your doctor first. They will tell you how to do this. If your treatment is stopped it should be done gradually over a minimum of 1 week. After stopping a short or long-term treatment with [Name to be completed nationally], you need to know that you may experience certain side effects, so-called withdrawal effects. These effects can include seizures, anxiety, difficulty sleeping, feeling sick (nausea), pain, sweating, shaking, headache, depression, feeling abnormal, dizziness, and feeling generally unwell. These effects usually occur within 48 hours after stopping [Name to be completed nationally]. 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

Stop using [Name to be completed nationally] and seek medical attention immediately if you notice any of the following symptoms:

- 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 9 skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

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

Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious:

- **severe skin reactions** that require immediate attention, swelling of the lips and face, skin rash and redness, and/or hair loss (these may be symptoms of a serious allergic reaction)
- **persistent stomach pain**, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas)
- **Breathing problems**, which if severe you may need emergency and intensive care to continue breathing normally.

- May cause a serious or life-threatening **allergic reaction** that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have rash when you get this type of reaction. It may cause you to be hospitalized or to stop [Name to be completed nationally]. Call your doctor right away if you have any of the following symptoms:
 - skin rash
 - hives
 - fever
 - swollen glands that do not go away
 - swelling of your lip and tongue
 - yellowing of your skin or of the whites of the eyes
 - unusual bruising or bleeding
 - severe fatigue or weakness
 - unexpected muscle pain
 - frequent infections

These symptoms may be the first signs of a serious reaction. A doctor should examine you to decide if you should continue taking [Name to be completed nationally].

- If you are on haemodialysis, tell your doctor if you develop muscle pain and/or weakness.

Other side effects include:

Very common (may affect more than 1 in 10 people)

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

Common (may affect up to 1 in 10 people)

- 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 thinking
- Convulsions, jerky movements, difficulty with speaking, loss of memory, tremor, difficulty sleeping, headache, sensitive skin, decreased sensation (numbness), 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, diarrhoea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
- Facial swelling, bruises, rash, itch, acne
- Joint pain, muscle pain, back pain, twitching
- Difficulties with erection (impotence)
- Swelling in the legs and arms, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
- Decrease in white blood cells, increase in weight
- Accidental injury, fracture, abrasion

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

Uncommon (may affect up to 1 in 100 people)

- Agitation (a state of chronic restlessness and unintentional and purposeless motions)
- Allergic reaction such as hives

- Decreased movement
- Racing heartbeat
- Difficulty swallowing
- Swelling that may involve the face, trunk and limbs
- Abnormal blood test results suggesting problems with the liver
- Mental impairment
- Fall
- Increase in blood glucose levels (most often observed in patients with diabetes)

Rare (may affect up to 1 in 1,000 people)

- Decrease in blood glucose levels (most often observed in patients with diabetes)
- Loss of consciousness
- • Trouble breathing, shallow breaths (respiratory depression)

Not known: frequency cannot be estimated from the available data

- suicidal thoughts
- Becoming dependent on [Name to be completed nationally] ('drug dependence')

After stopping a short or long-term treatment with [Name to be completed nationally], you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking [Name to be completed nationally]").

After marketing [Name to be completed nationally] the following side effects have been reported:

- Decreased platelets (blood clotting cells)
- Hallucinations
- Problems with abnormal movements such as writhing, jerking movements and stiffness
- Ringing in the ears
- Yellowing of the skin and eyes (jaundice), inflammation of the liver
- Acute kidney failure, incontinence
- Increased breast tissue, breast enlargement
- Adverse events following the abrupt discontinuation of gabapentin (anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
- Breakdown of muscle fibers (rhabdomyolysis)
- Change in blood test results (creatinine phosphokinase increased)
- Problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation
- Low blood sodium level
- Anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)

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 X

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. 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 [Name to be completed nationally] contains

The active substance in [Name to be completed nationally] is gabapentin
[Name to be completed nationally] 100 mg hard capsules contain 100 mg of gabapentin.
[Name to be completed nationally] 300 mg hard capsules contain 300 mg gabapentin.
[Name to be completed nationally] 400 mg hard capsules contain 400 mg gabapentin.

The other ingredients that are present in the capsule contents are: lactose monohydrate, maize starch and talc.

The capsule shell contains: gelatin, titanium dioxide (E171) and sodium lauryl sulphate.
Additionally the 300 mg capsule shell contains iron oxide yellow (E172) and the 400 mg capsules shell contains iron oxide yellow (E172) and iron oxide red (E172).

The printing ink contains Shellac and Black iron oxide (E172).

What [Name to be completed nationally] looks like and contents of the pack

- [Name to be completed nationally] 100 mg hard capsules are Size '3' hard gelatin capsules with white opaque cap and white opaque body, imprinted with a 'G' on cap and '456' on body with black ink, filled with white to off-white powder.

- [Name to be completed nationally] 300 mg hard capsules are Size '1' hard gelatin capsules with light yellow to yellow cap and light yellow to yellow body, imprinted with a 'G' on cap and '457' on body with black ink, filled with white to off-white powder.

- [Name to be completed nationally] 400 mg hard capsules are Size '0' hard gelatin capsules with light orange to orange cap and light orange to orange body, imprinted with a 'G' on cap and '458' on body with black ink filled with white to off-white powder.

[Name to be completed nationally] 100 mg hard capsules are packaged in blisters supplied in boxes containing: 1, 10, 30, 45, 50, 60, 84, 90, 100, 120, 180 and 200 and containers with 20, 50, 100, 200, 200 (multi-pack containing 2 bottles of 100 capsules), 300, 500 and 1000 hard capsules .

[Name to be completed nationally] 300 mg hard capsules are packaged in blisters supplied in boxes containing: 1, 10, 30, 45, 50, 60, 84, 90, 100, 120, 180 and 200 and containers with 50, 100, 200, 200 (multi-pack containing 2 bottles of 100 capsules), 300, 500 and 1000 hard capsules .

[Name to be completed nationally] 400 mg hard capsules are packaged in blisters supplied in boxes containing: 1, 10, 30, 45, 50, 60, 84, 90, 100, 120, 180 and 200 and containers with 50, 100, 200, 200 (multi-pack containing 2 bottles of 100 capsules), 300, 500 and 1000 hard capsules .

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning voor het in de handel brengen

Glenmark Arzneimittel GmbH,
Industriestr. 31, 82194 Gröbenzell,
Duitsland

Fabrikant

Glenmark Pharmaceuticals s.r.o.

Fibichova 143
56617 Vysoke Myto
Tsjechië.

In het register ingeschreven onder:

Gabapentine 100 mg harde capsules: RVG 120698

Gabapentine 300 mg harde capsules: RVG 120708

Gabapentine 400 mg harde capsules: RVG 120709

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Gabapentine Glenmark 100 / 300 / 400 mg harde capsules
Duitsland	Gabapentin Glenmark 100mg, 300mg, 400mg Hartkapseln
Spanje	Gabapentin Viso Farmacéutica 100 mg, 300 mg, 400 mg Hard Capsules
Slowakije	Gabapentin Glenmark 100 mg, 300 mg, 400 mg tvrde kapsuly

Deze bijsluiter is voor het laatst goedgekeurd in januari 2023.