

PACKAGE LEAFLET

Package leaflet: Information for the user

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 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 Gabapentin is and what it is used for
2. What you need to know before you take Gabapentin
3. How to take Gabapentin
4. Possible side effects
5. How to store Gabapentin
6. Contents of the pack and other information

1. What Gabapentin is and what it is used for

Gabapentin 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 Gabapentin is gabapentin.

Epilepsy: Gabapentin 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 Gabapentin for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Gabapentin in addition to your current treatment unless told otherwise. Gabapentin can also be used on its own to treat adults and children over 12 years of age.

Peripheral neuropathic pain: Gabapentin is used to treat 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 Gabapentin

Do not take Gabapentin:

- 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 Gabapentin if:

- you suffer from kidney problems, your doctor may prescribe a different dosing schedule
- you are on haemodialysis (to remove waste products because of kidney failure), tell your doctor if you develop muscle pain and/or weakness
- 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

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.

During treatment

Gabapentin may cause dizziness and drowsiness, leading to increased accidental injuries and falls (see section 4). Loss of consciousness and confusion have also been reported from the post-marketing experience. You should be cautious until you know how this medication affects you.

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.

Important information about potentially serious reactions

A small number of people taking Gabapentin 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 the symptoms to look out for while you are taking Gabapentin.

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.

Children

Gabapentin is not recommended for use in children under 6 years of age.

Other medicines and Gabapentin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. 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 Gabapentin. In addition, combination of Gabapentin with opioids may cause symptoms like sleepiness and/or decrease in breathing.

Antacids for indigestion

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

Gabapentin is not expected to interact with other antiepileptic medicines such as phenobarbital, phenytoin, sodium valproate or carbamazepine or the oral contraceptive pill containing norethindrone with or without ethinyl estradiol.

Gabapentin may interfere with some laboratory tests. If you require a urine test tell your doctor or hospital that you are taking gabapentin.

Gabapentin with food

Gabapentin can be taken with or without food.

Pregnancy and 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

Gabapentin 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.

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Gabapentin. 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 is passed on through human milk. Because the effect on the nursing infant is unknown, it is not recommended to breast-feed while using gabapentin.

Fertility

There is no effect on fertility in animal studies.

Driving and using machines

Gabapentin may cause 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.

Gabapentin contains lactose and sodium

Gabapentin 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.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Gabapentin

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

Your doctor will determine what dose is appropriate for you.

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

This medicine may be taken with or without food.

Continue taking gabapentin until your doctor tells you to stop.

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 recommended 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 recommended dose to control epilepsy is 25-35 mg per kg of body weight each per day. It is usually given in 3 divided doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.

Gabapentin 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 recommended 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.

People with 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 if you are undergoing haemodialysis.

Elderly patient (over 65 years of age)

You should take the normal recommended doses of Gabapentin as listed above 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 Gabapentin is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

If you take more Gabapentin 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 Gabapentin 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.

You may fall unconscious if you take too much gabapentin whilst also taking other medicines which cause drowsiness.

If you forget to take Gabapentin

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 Gabapentin

Do not stop taking Gabapentin 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 Gabapentin 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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:

- breathing problems, which if severe you may need emergency and intensive care to continue breathing normally

Common (may affect up to 1 in 10 people):

- chest infections which may cause difficulty breathing and/or coughing. If you have fever, chills and a cough which may produce phlegm or occasionally blood, fluid on the lungs or pain when breathing, these may indicate that you have serious chest infections such as pneumonia
- an increase in the number of infections you get causing fever, severe chills, sore throat or mouth ulcers. These may indicate that you have a reduced number of white blood cells in the body.
- seizures

Not known (cannot be estimated from the available data):

- severe skin reactions that require immediate medical attention, skin rash and redness, blistering and bleeding from the lips, eyes or mouth, or skin peeling accompanied by fever, severe itching or hives. These may indicate Stevens-Johnson syndrome
- anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)
- yellowing of your skin or whites of your eyes, dark urine, pale stools, tiredness, fever, nausea, weakness, drowsiness or abdominal pain. These may indicate you have serious problems with your liver
- persistent stomach pain which radiates to your back, feeling sick or being sick. These may indicate that you have problems with your pancreas
- passing little or no urine, pain, discomfort or difficulty when passing urine, cloudy urine or lower back pain. These may indicate a serious problem with your kidneys
- muscle pain, with or without weakness, dark urine or an increase of muscle proteins or creatine phosphokinase in your blood. These may indicate your muscles are breaking down, a condition called rhabdomyolysis
- Gabapentin 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 hospitalised or to stop gabapentin. 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 face, lips, tongue and/or throat
 - 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 gabapentin.

- 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 more than 1 in 100 people):

- pneumonia, respiratory infection, urinary tract infection, general infections, inflammation of the ear
- shortness of breath, stuffy nose
- an increase or loss of appetite (anorexia)
- anger towards others, confusion, fluctuation in mood, depression, anxiety, nervousness, difficulty with thinking

- difficulty with speaking, loss of memory, shaking/tremor, increase in jerky movements, difficulty sleeping, headache, tingling or pins and needles in your hands and feet, decreased sensation (numbness), difficulty with coordination, unusual rapid eye movement, increased, decreased or absent reflexes
- blurred vision, double vision
- a spinning sensation known as vertigo
- high blood pressure, flushing or dilation of blood vessels
- vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhoea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
- facial swelling, bruises resulting from physical injury, rash, itch, acne
- joint pain, muscle pain, back pain, twitching
- difficulties getting or maintaining an erection (impotence)
- fluid retention, swelling in the legs and arms or, difficulty with walking, weakness, pain, general feeling of being unwell, flu-like symptoms
- increase in weight
- accidental injury, broken bones, damage to your skin

Uncommon (may affect up to 1 in 100 people):

- allergic reactions such as hives
- reduced movement
- racing heartbeat you may feel as a thumping in your chest
- swelling that may involve the face, trunk and limbs
- an increase in liver enzymes and bilirubin in your blood
- difficulty thinking
- fall
- high blood sugar (most often observed in patients with diabetes)
- agitation (a state of chronic restlessness and unintentional and purposeless motions)
- difficulty swallowing

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

- loss of consciousness
- low blood sugar (most often observed in patients with diabetes)
- trouble breathing, shallow breaths (respiratory depression)

Not known (cannot be estimated from the available data):

- decreased platelets (blood clotting cells) causing unexplained bruising or bleeding
- seeing or hearing things that aren't there (hallucinations)
- problems with abnormal movements such as writhing, jerking movements and stiffness
- ringing in the ears
- uncontrollable, involuntary passing of urine
- side effects following the abrupt discontinuation of gabapentin may occur (such as anxiety, difficulty sleeping, feeling sick, pain, sweating) or chest pain
- blood glucose changes in patients with diabetes
- reduced sodium concentration in blood (hyponatraemia)
- hair loss
- increase in breast size or development of breasts in males
- other problems affecting the ability to have sex such as loss of sex drive, problems with male ejaculations or inability to achieve orgasm in females

Additional side effects in children

The following side effect was commonly reported:

- Aggressive behaviour

- Jerky movements

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.

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 Gabapentin

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the blister and the outer carton after “EXP”. The expiry date refers to the last day of that month.

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 Gabapentin contains

The active substance is gabapentin.

Each hard capsule contains either 100 mg, 300 mg or 400 mg gabapentin.

The other ingredients are:

Capsule contents: lactose anhydrous (see section 2, ‘Gabapentin contains lactose anhydrous’), maize starch and talc.

Capsule shell: gelatin, titanium dioxide (E171) and sodium lauryl sulphate.

The 300 mg capsules also contain yellow iron oxide (E172).

The 400 mg capsules also contain red and yellow iron oxides (E172)

What Gabapentin looks like and contents of the pack

Capsule, hard. The 100 mg capsules are white, the 300 mg are yellow and the 400 mg capsules are orange.

Each capsule contains a white powder.

Gabapentin is available in blister packs of 10, 20, 30, 50, 90, 100, 200 (2x100), 250, 500 (5x100) and 1,000 (10x100) capsules and unit dose blister packs containing 20x1, 60x1 and 100x1 capsules.

Gabapentin is also available in bottles containing 50, 100 and 250 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate,
Grange Road, Dublin 13.

Manufacturer

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate,
Grange Road, Dublin 13.

Mylan Hungary Kft., Mylan utca 1, Komarom 2900, Hungary

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