

## **Package leaflet: Information for the user**

**Gabapentin 100 mg hard capsules**

**Gabapentin 300 mg hard capsules**

**Gabapentin 400 mg hard 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 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.

### **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). The doctor treating you or your child 6 years of age and older will prescribe Gabapentin for you 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 Gabapentin in addition to the 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 (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
- 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 Gabapentin.
- 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

### **Dependence**

Some people may become dependent on Gabapentin (a need to keep taking the medicine). They may have withdrawal effects when they stop using Gabapentin (see section 3, “How to take Gabapentin” and “If you stop taking Gabapentin”). If you have concerns that you may become dependent on Gabapentin, it is important that you consult your doctor.

If you notice any of the following signs whilst taking Gabapentin, 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.

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**

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 ‘*Stop using Gabapentin and seek medical attention immediately if you notice any of the following symptoms*’**

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 Gabapentin**

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 Gabapentin. In addition, combination of Gabapentin with opioids may cause sleepiness, sedation, decrease in breathing, or death.

#### 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 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.

#### **Gabapentin with food**

Gabapentin 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**

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.

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 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, the active substance of Gabapentin, is passed on through human milk. Because the effect on the baby 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 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.

**Gabapentin contains Sodium:**

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. 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.

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 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 Gabapentin 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.

**Method of administration**

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

Continue taking Gabapentin until your doctor tells you to stop.

**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.

#### **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 suddenly stop** taking Gabapentin. If you want to stop taking Gabapentin, 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 Gabapentin, 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 Gabapentin. 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**

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

**Stop using Gabapentin 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 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).

**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**
- **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 hospitalized 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 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 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 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
- 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)
- Difficulty swallowing

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

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

**Not known: frequency cannot be estimated from based on the available data**

- Becoming dependent on Gabapentin ('drug dependence')

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

**After marketing Gabapentin the following side effects have been reported:**

- Decreased platelets (blood clotting cells)
- Suicidal thoughts, 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

**Ireland**

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://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 use this medicine after the expiry date which is stated on the blister, bottle and carton after "EXP". The expiry date refers to the last day of that month.

Blister: Do not store above 30°C. Store in the original package, in order to protect from moisture.

HDPE bottle: Store in the original package, in order to protect from moisture. Keep the bottle tightly closed.

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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Gabapentin contains**

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

The other ingredients in Gabapentin are:

Capsule contents: maize starch, copovidone (E1201), poloxamer 407 and magnesium stearate (E470b).

Capsule shell: gelatin and sodium laurilsulfate.

The capsules contain the colouring titanium dioxide (E171), iron oxide red (E172) (400 mg hard capsules) and iron oxide yellow (E172) (300 mg and 400 mg hard capsules). The printing ink used on capsules contains shellac (E904), propylene glycol (E1520), ammonia solution concentrated and indigo carmine aluminium lake (E132).

### **What Gabapentin looks like and contents of the pack**

Gabapentin 100 mg hard capsules are opaque white/opaque white coloured size "3", approximately 15.40 to 16.20 mm in length, hard gelatin capsules imprinted with "G 100" on cap with blue ink containing white to off white powder.

Gabapentin 300 mg hard capsules are opaque yellow/opaque yellow coloured size "1", approximately 18.90 to 19.70 mm in length, hard gelatin capsules imprinted with "G 300" on cap with blue ink containing white to off white powder.

Gabapentin 400 mg hard capsules are opaque orange/opaque orange coloured size "0", approximately 21.00 to 21.80 mm in length, hard gelatin capsules imprinted with "G 400" on cap with blue ink containing white to off white powder.

Capsules are packed in PVC/PVdC- alu blister, alu-alu blister or HDPE bottle.

Pack sizes:

PVC/PVdC- alu blister and alu-alu blister: 20, 30, 50, 60, 84, 90, 98, 100, 200, 500 and 1000 capsules.

HDPE bottle: 100 and 500 capsules.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Accord Healthcare Ireland Ltd,  
Euro House,  
Euro Business Park,  
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#### **Manufacturer**

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**This medicinal product is authorised in the Member States of the EEA under the following names:**

<b>Member States</b>	<b>Invented Names</b>
Austria	Gabapentin Accord 100/300/400 mg Hartkapseln
Cyprus	Gabapentin Accord 300/400 mg σκληρά καψάκια
Germany	Gabapentin Accord 100/300/400 mg Hartkapseln
Denmark	Gabapentin Accord 300/400 mg hårde kapsler
Estonia	Gabapentin Accord
Finland	Gabapentin Accord 300/400 mg kapselit, kovat
Ireland	Gabapentin 100/300/400 mg hard capsules
Lithuania	Gabapentino Accord 100/300/400 mg kietosios kapsulės
Malta	Gabapentin 100/300 mg hard capsules
Netherland	Gabapentine Accord 100/300/400 mg harde capsules
Norway	Gabapentin Accord 100/300/400 mg kapsler, harde
Poland	Gabacol
Sweden	Gabapentin Accord 100/300/400 mg hårda kapslar
United Kingdom	Gabapentin Accord 100/300/400 mg hard capsules

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