

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

- allergic reaction such as hives
- difficulty swallowing
- 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)
- agitation (a state of chronic restlessness and unintentional and purposeless motions)

### 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 the available data):

- decreased platelets (blood clotting cells)
- hallucinations
- problems with abnormal movements such as writhing, jerking movements and stiffness
- ringing in the ears
- a group of side effects that could include swollen lymph nodes (isolated small raised lumps under the skin), fever, rash, and inflammation of the liver occurring together
- 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 fibres (rhabdomyolysis)
- muscle spasms
- 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, pharmacist or nurse. 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

### 5 How to store Gabapentin capsules

Keep out of the sight and reach of children. Do not store the capsules above 25°C. Do not use Gabapentin capsules 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 Contents of the pack and other information

#### What Gabapentin capsules contain

The active substance (the ingredient that makes the medicine work) is gabapentin. Each capsule contains either 100mg, 300mg or 400mg gabapentin.

The other ingredients in the capsules are lactose monohydrate, maize starch, talc. The capsule shell contains titanium dioxide (E171) and gelatin, yellow iron oxide (E172) (300mg and 400mg capsules) and red iron oxide (E172) (400mg capsules only).

The printing ink contains Shellac (E904), propylene glycol (E1520), black iron oxide (E172) and potassium hydroxide (E525).

#### What Gabapentin capsules look like and contents of the pack

Gabapentin 100mg capsules are size 3, white-white, hard gelatin capsules printed with C and GJ

Gabapentin 300mg capsules are size 1, yellow-yellow, hard gelatin capsules printed with C and GK

Gabapentin 400mg capsules are Size 0, orange-orange hard gelatin capsules printed with C and GL.

The packs contain: 100 capsules.

#### Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

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accord

Package Leaflet: Information for the patient

## Gabapentin Accord-UK 100mg, 300mg and 400mg capsules

### 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

### What is 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 belong to a group of medicines used to treat:

- **various forms of epilepsy** – Gabapentin capsules can be used on their own in adults and children aged *12 years and over* or in combination with other medicines to treat epilepsy in adults and children *aged 6 years and over*.
- **peripheral neuropathic pain** - This is long lasting pain caused by damage to the nerves.

### 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 (see section 6).

#### Warnings and precautions

#### Talk to your doctor, pharmacist or nurse before taking Gabapentin capsules

- if you suffer from **kidney problems** your doctor may prescribe a different dosing schedule
- if you suffer with different types of **seizures including absences**.
- 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.

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.

#### 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 these 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'

## Other medicines and Gabapentin capsules

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 capsules. In addition, combination of Gabapentin capsules with opioids may cause symptoms like sleepiness and/or decrease in breathing.
- antacids containing aluminium and magnesium (used to reduce stomach acid)- if taken at the same time, absorption of Gabapentin capsules from the stomach may be reduced. It is therefore recommended that Gabapentin capsules are taken at least two hours after taking an antacid.

## Urine Tests

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

## Pregnancy, breastfeeding and fertility

### Pregnancy

Gabapentin capsules should not be taken during pregnancy, unless advised by your doctor.

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Gabapentin capsules. Other medicines used to treat seizures may increase the risk of harm to the foetus, 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 stop taking this medicine as this may lead to breakthrough seizures, which could have serious consequences for you and your baby.

### Breast-feeding

If you are taking Gabapentin capsules, do not breastfeed, unless advised to by your doctor, as this medicine will pass into breast milk and may harm the baby.

### Fertility

There is no effect on fertility in animal studies.

## Driving and using machines

When taking Gabapentin capsules you may become drowsy, dizzy or feel tired, especially at the start of treatment or after a dose increase. Make sure you are not affected before driving or operating machinery.

## Gabapentin capsules contain lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3 How to take Gabapentin capsules

Always take Gabapentin capsules exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. Gabapentin capsules are usually taken three times a day (morning, afternoon and evening). Always swallow the capsules whole with plenty of water, with or without food. Your doctor will determine what dose is appropriate for you. If you are an elderly patient (over 65 years old), have kidney disease or are having haemodialysis, you should take Gabapentin capsules as prescribed by your doctor. Continue taking Gabapentin capsules until your doctor tells you to stop.

## Dosage

### • **Epilepsy:**

#### **Adults and children aged 12 years or over:**

The usual starting dose is between 300mg and 900mg each day. The dose may then be increased gradually to a maximum of 3600mg each day.

#### **Children aged 6 years and above:**

The dose depends on the body weight of your child. The treatment is started with a low initial dose which is gradually increased over a period of about 3 days. The usual dose to control epilepsy is 25-35mg per kg per day. Gabapentin capsules are not recommended for use in children below 6 years of age.

### • **Peripheral neuropathic pain:**

The usual starting dose is between 300mg and 900mg each day. The dose may then be increased gradually to a maximum of 3600mg each day.

## If you take more Gabapentin capsules than you should

If you or someone else accidentally takes too many capsules, or if you think a child has swallowed any, contact your doctor or go to your nearest hospital casualty department immediately. As Gabapentin capsules may make you drowsy, it is recommended that you ask someone else to drive you to the doctor or hospital, or that you call an

ambulance. Symptoms of an overdose are dizziness, double vision, slurred speech, drowsiness or tiredness, loss of consciousness and mild diarrhoea. Overdose of gabapentin, particularly in combination with other CNS depressant medications, may result in coma.

## If you forget to take Gabapentin capsules

If you miss 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 capsules

Do not stop taking this medicine suddenly, as your symptoms may get worse. Your doctor will reduce the dose gradually, you may experience anxiety, difficulty sleeping, feeling sick, pain, sweating.

## 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
- 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)
- 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 liver or blood cells. You may or may not have a rash when you get this type of reaction. It may cause you to be hospitalised or to stop Gabapentin capsules.

**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 lips 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 Capsules.

- 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, sensations such as pins and needles, 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, runny 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, itchy skin, 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. Respiratory tract infections, inflammation of the middle ear and ear drum, convulsions and bronchitis were also reported.