

Package leaflet: Information for the user
Gabapentin Accord 100 mg, hard capsules
Gabapentin Accord 300 mg, hard capsules
Gabapentin Accord 400 mg, hard capsules

Gabapentin

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may be harmful to others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect that is not mentioned in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Gabapentin Accord and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How should you store this medicine?
6. Contents of the package and other information

1. What is Gabapentin Accord and what is it used for?

This medicine belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long-lasting pain caused by nerve damage).

The active substance in this medicine is gabapentin.

This medicine is used for the treatment of

- Various forms of epilepsy (seizures that initially remain limited to certain parts of the brain, regardless of whether the seizure spreads to other parts of the brain). The doctor who treats you or your child who is at least 6 years old will prescribe this medicine for the treatment of epilepsy if the condition is not fully controlled with the current treatment. You or your child who is at least 6 years old should use this medicine in addition to the current treatment, unless the doctor prescribes otherwise. This medicine can also be used on its own to treat adults and children over 12 years old.
- Peripheral neuropathic pain (long-lasting pain caused by nerve damage). Peripheral neuropathic pain (mainly occurring in the arms and/or legs) can be caused by various conditions, such as diabetes and shingles. The pain can be described as hot, burning or throbbing pain, shooting, stabbing, sharp pain, cramps, gnawing pain, tingling, stiffness, pins and needles, etc.

2. When should you not use this medicine or be extra careful? When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine

- if you suffer from a kidney disorder, your doctor may prescribe a different dosing schedule
- Before you start using this medicine, you should tell your doctor if you have ever abused or been dependent on alcohol, prescription drugs, or illegal drugs. This may mean that you have a higher risk of dependence on Gabapentin Accord.
- if your blood is being dialyzed (to remove waste products due to a kidney disorder), inform your doctor if you experience muscle pain and/or weakness
- if you develop symptoms such as persistent stomach pain, if you feel sick or are sick, contact your doctor immediately as these may be symptoms of acute pancreatitis (an inflamed pancreas)
- if you have complaints affecting the central nervous system or breathing, or if you are older than 65 years, your doctor may prescribe a different dosing schedule.

Dependence (addiction)

Some people may become dependent on this medicine (develop a need to continue using, become addicted). If they stop taking this medicine, they may experience withdrawal symptoms (see section 3, "How to use this medicine?" and "If you stop using this medicine"). If you are concerned that you may become dependent on (addicted to) this medicine, it is important to consult your doctor.

If you notice any of the following signs while using this medicine, it may indicate that you have become dependent (addicted).

You feel the need to use the medicine longer than advised by your prescribing doctor advised

You use the medicine for reasons other than those for which it was prescribed

You have tried multiple times without success to stop or control the use of the

You have tried several times without success to stop or reduce the use of the medicine start using the medicine again

If you notice one or more of these, contact your doctor to discuss the best treatment for you, middle will use again

of self-harm or suicide. If you have such thoughts at any time, contact to discuss, such as when it is appropriate to stop and how to do this safely.

A small number of people treated with antiepileptic drugs such as gabapentin have thoughts had about self-harm or suicide. If you have such thoughts at any time, contact then contact your doctor immediately.

Important information about possible serious reactions

Serious forms of skin rash have been reported in connection with gabapentin, such as the syndrome of Stevens-Johnson, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS). Stop using gabapentin and contact your doctor immediately if you notice any of the symptoms of these serious skin reactions, which are described in section 4.

Read the description of these symptoms in section 4 of this leaflet under 'Stop using this medicine and seek immediate medical help if you experience any of the following complaints' of one of the following complaints

be life-threatening and can lead to kidney problems. You may also notice discoloration of your urine and a change in blood test results (especially an increase in creatine phosphokinase). Contact your doctor immediately if you experience any of these signs or symptoms. Are you taking any other medicines?

Are you taking any other medicines besides Gabapentin Accord, have you done so recently, or

is there a possibility that you will take other medicines in the near future? Then tell

your doctor or pharmacist. Inform your doctor (or pharmacist) especially if you are taking medicines for seizures, sleep disorders, depression, anxiety disorders, or other inform your doctor or pharmacist. Specifically, inform your doctor (or pharmacist) if you medications for convulsions, sleep disorders, depression, anxiety disorders, or other neurological or psychiatric problems, or if you have recently taken them.

Medicines containing opioids, such as morphine

If you are taking medicines that contain opioids (such as morphine), you must inform your doctor or pharmacist, because opioids can enhance the effect of this medicine. Furthermore, the combination of this medicine with opioids can cause drowsiness, sedation, slower breathing, or death. Antacids for indigestion (digestive disorder)

If this medicine is taken at the same time as antacids containing aluminum and magnesium, it can limit the absorption of Gabapentin Accord from the stomach. It is therefore recommended to take this medicine at least two hours after an antacid. Gabapentin Accord take.

oral contraceptives.

- can affect the results of some laboratory tests. If you need to provide a urine sample for testing, inform your doctor or hospital about what you are using.
- What should you pay attention to with food? This medicine can be taken with or without food.

Pregnancy, breastfeeding, and fertility

Are you pregnant or do you think you might be pregnant? Then contact your doctor immediately and discuss

Pregnancy, breastfeeding, and fertility

- Are you pregnant or do you think you might be pregnant? Then contact your doctor immediately and discuss the possible risks of the medication you are using on your unborn child
- Do not suddenly stop your treatment before discussing it with your doctor.
- Do you want to become pregnant? Then contact your doctor or pharmacist as early as possible before you become pregnant. with your doctor or pharmacist
- Are you breastfeeding or planning to breastfeed? Then contact your doctor or pharmacist before using this medication.

Pregnancy

Gabapentin can be used during the first trimester of pregnancy if necessary.

When you plan to become pregnant, are pregnant, or suspect you are pregnant, contact your doctor immediately.

If you have become pregnant and have epilepsy, it is important not to stop taking your medication without consulting your doctor first, as this may worsen your condition. Worsening of your epilepsy can endanger you and your unborn child.

In a study with data from women in Scandinavian countries who took gabapentin during the first 3 months of pregnancy, there was no increased risk of birth defects or problems with brain function development (neurological developmental disorders). However, babies of women who took gabapentin during pregnancy had an increased risk of low birth weight and preterm birth.

If you use gabapentin during pregnancy, it may lead to withdrawal symptoms in newborns. This risk may be higher when gabapentin is used together with opioid painkillers (medicines for the treatment of severe pain).

Inform your doctor immediately if you become pregnant, suspect you are pregnant, or plan to become pregnant while using this medicine. Do not suddenly stop using this medicine as this may lead to a breakthrough seizure that can have serious consequences for you and your child.

Breastfeeding

Gabapentin, the active substance of this medicine, passes into breast milk. The effect of this on the child is unknown, therefore breastfeeding is not recommended during the use of this medicine.

Fertility

Animal studies have shown no effect on fertility.

Driving and using machines

This medicine can cause dizziness, drowsiness, and fatigue. You should not drive a vehicle, operate complex machinery, or engage in other potentially hazardous activities until you know

whether this medicine affects your ability to perform these activities. Gabapentin Accord contains sodium

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

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist. Do not use more of this medicine than the prescribed dose.

Your doctor will determine which dose is suitable for you.

Epilepsy, the recommended dosage is:

Adults and adolescents up to 18 years:

Take the prescribed number of capsules. Generally, your doctor will gradually increase your dose. The starting dose is usually between 300 mg and 900 mg per day. Then the dose can be increased stepwise on prescription by your doctor to a maximum of 3600 mg per day. Your doctor will tell you to take these in three separate doses, that is, one in the morning, one in the afternoon, and one in the evening.

Children 6 years and older

The dose your child receives is determined by your doctor based on your child's weight. The treatment is started with a low initial dose that is gradually increased over a period of approximately 3 days. The usual dose to control epilepsy is 25-35 mg per kg per day. Usually, the capsules are taken in three separate doses spread throughout the day, usually one in the morning, one in the afternoon and one in the evening.

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

Peripheral neuropathic pain, the recommended dosage is

Adults

Take the number of capsules prescribed by your doctor. Generally, your doctor will slowly increase your dose. The starting dose is usually between 300 mg and 900 mg per day. Then the dose can be increased stepwise as prescribed by your doctor up to a maximum of 3600 mg per day. Your doctor will tell you to take these in three separate doses, that is, one in the morning, one in the afternoon and one in the evening.

If you suffer from a kidney disorder or if your blood needs to be dialyzed

Your doctor may prescribe a different dosing schedule and/or a different dose if you have a condition affecting your kidneys or if your blood needs to be dialyzed.

When you are an elderly patient (over 65 years old)

You can use the normal dose of this medicine unless you have kidney problems. If you have kidney problems, your doctor may prescribe a different dosing schedule and/or different dose prescribe.

Consult your doctor or pharmacist as soon as possible if you think the effect of this medicine is too strong or is too weak.

Method of administration

This medicine is intended for oral use. Always take the capsules with a generous amount of water.

Continue using this medicine until your doctor tells you to stop.

Have you used too much of this medicine?

Taking doses higher than recommended can lead to an increased risk of side effects including loss of consciousness, dizziness, double vision, unclear speech, drowsiness, and diarrhea. Immediately inform your doctor or go to the emergency department of the nearest hospital if you take more of this medicine than your doctor prescribed. Take the capsules you did not take, along with the packaging and label, so that the hospital can easily see which medicine you have taken. Have you forgotten to use this medicine?

If you forget to take a dose, take it as soon as you remember,

unless it is already time for your next dose. Do not take a double dose to make up for a forgotten dose. If you stop using this medicine

Do not stop using this medicine suddenly. If you want to stop using this medicine, discuss it middle

Do not stop using this medication suddenly. If you want to stop using this medication, discuss this then first with your doctor. Your doctor will tell you how to stop. If your treatment is discontinued, you should gradually reduce the dosage over a period of at least 1 week. After stopping a short or long treatment with this medicine, you should be aware that you may experience certain side effects, known as withdrawal symptoms. These symptoms may include seizures, anxiety, sleep problems, nausea, pain, sweating, trembling, headache, depression, abnormal sensation, dizziness, and general malaise. These symptoms usually occur within 48 hours after stopping this medicine. If you experience withdrawal symptoms, you should contact your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can also have side effects, although not everyone will experience them. to make.

of the following symptoms: red, flat, target-like or round spots on the trunk, often with blisters in the

- center, peeling, sores of the mouth, throat, nose, genitals, and eyes. These severe forms of skin rash may be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis). symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- widespread rash, high body temperature, and swollen lymph nodes (DRESS or drug hypersensitivity syndrome).

Contact your doctor immediately if you experience any of the following symptoms after taking this medication, as they may be serious: persistent abdominal pain, nausea, and vomiting, as these may be symptoms of

- acute pancreatitis (an inflamed pancreas) breathing problems, depending on the severity of which you may need emergency care and
- intensive care to continue breathing normally This medicine can cause a severe or life-threatening allergic reaction, which may affect
- your skin or other parts of your body such as your liver or your blood cells. blood cells. to be hospitalized or stop taking this medicine. Contact your doctor immediately if you experience any of the following symptoms: Skin rash and redness and/or hair loss contact your doctor if you experience any of the following symptoms:
 - fever
 - furuncles
 - fever
 - swelling of the glands that does not decrease
 - swelling of your lip, face, and tongue
 - yellowing of your skin or the whites of your eyes
 - unusual bruising or bleeding
 - severe fatigue or weakness
 - unexpected muscle pain
 - frequent infections with bacteria or viruses (infections)

These symptoms may be the first signs of a serious reaction. A doctor must examine you to decide whether you should continue using this medicine.

- If you need to undergo hemodialysis, inform your doctor if you experience muscle pain and/or –weakness occurs.

Other side effects include:

Very common (occur in more than 1 in 10 users):

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

Common (occur in less than 1 in 10 users):

- Pneumonia, respiratory infections, urinary tract infection, ear infection or other infections
- Low white blood cell count
- Loss of appetite (anorexia), increased appetite
- Outbursts of anger directed at others, confusion, mood swings, depression, anxiety, nervousness, difficulty thinking
- Seizure with muscle twitching (convulsions), spastic movements, difficulty speaking, memory loss, trembling, difficulty sleeping, headache, sensitive skin, reduced sensation (numbness), coordination disorders, unusual eye movements, increased, decreased or absent reflexes
- Blurred vision, double vision
- Vertigo
- High blood pressure, flushing or vasodilation
- Difficulty breathing, inflammation of the airways with coughing and producing phlegm (bronchitis), sore throat, cough, dry nose
- Vomiting (being sick), nausea (feeling sick), dental problems, inflamed gums, diarrhea, abdominal pain, stomach and intestinal disorders, constipation, dry mouth or throat, flatulence
- Swelling of the face, bruising, rash, itching, (youth) acne
- Joint pain, muscle pain, back pain, muscle twitching
- Erectile problems (impotence)
- Swelling of arms and legs, difficulty walking, weakness, pain, feeling unwell, flu-like symptoms
- Decrease in white blood cell count, weight gain
- Unintentional injury, bone fracture, abrasion

Additionally, aggressive behavior and spastic movements were often reported in clinical studies in children. reported.

Agitation (a state of prolonged restlessness and unintended and aimless

- movements)Allergic reaction, for example hives Reduced movement
- Rapid heartbeat
- Swelling involving the face, trunk, and limbs
- Abnormal blood test results that may indicate liver problems
- Mental deterioration
- Abnormal blood test results that could indicate liver problems
- Increased blood sugar levels (most observed in patients with diabetes)
- Fall
- Increased blood sugar levels (most commonly observed in patients with diabetes)

Rare (occur in less than 1 in 1,000 users):

- Lowered blood sugar levels (most observed in patients with diabetes)
- Loss of consciousness

- Difficulty breathing, shallow breathing (respiratory depression)

Not known (the frequency cannot be determined from the available data):

- Becoming dependent on this medicine ('drug dependence' or addiction)

After stopping a short or long treatment with this medicine, you should be aware that you may experience certain side effects, known as withdrawal symptoms (see "If you stop using this medicine").

The following side effects have been reported after the medicine was marketed:

- Decrease in platelets (cells that promote blood clotting)
- Thoughts of suicide, hallucinations (perceptions (seeing, hearing, smelling, feeling) of things that are not there)
- Problems with abnormal movements, such as writhing, spastic movements and stiffness
Ringing in the ears
- Tinnitus
- Acute kidney failure, incontinence
- Enlargement of breast tissue, breast enlargement
- Side effects due to abrupt discontinuation of gabapentin
- Side effects due to abrupt discontinuation of gabapentin (anxiety, difficulty with sleeping, feeling sick, pain, sweating), chest pain
- Breakdown of muscle tissue with symptoms such as muscle cramps, fever, and reddish-brown
- discoloration of the urine (rhabdomyolysis)
- Change in blood test results (elevated creatine phosphokinase)
- Problems with sexual functioning, including inability to achieve orgasm and delayed ejaculation
- Low sodium levels in the blood, which can lead to altered consciousness
- Anaphylaxis (severe, potentially life-threatening allergic reaction with difficulty breathing, swelling of the lips, throat, and tongue, and lowered blood pressure (hypotension) requiring emergency treatment)

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the blister pack, the bottle and the box after "EXP". It shows a month and a year. The last day of that month is the expiration date.

Blister pack: Store below 30°C. Store in the original packaging to protect against moisture.

HDPE bottle: Store in the original packaging to protect against moisture. Keep the bottle tightly closed.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

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

The other substances in this medicine are:

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

Capsule shell: gelatin and sodium lauryl sulfate.

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

What does Gabapentin Accord look like and how much is in a package?

Gabapentin Accord 100 mg, hard capsules are opaque white/opaque white hard gelatin capsules size "3", approximately 15.40 to 16.20 mm long with the imprint "G 100" on the cap in blue ink, containing a white to off-white powder.

Gabapentin Accord 300 mg, hard capsules are opaque yellow/opaque yellow hard gelatin capsules size "1", approximately 18.90 to 19.70 mm long with the imprint "G 300" on the cap in blue ink, containing a white to off-white powder.

Gabapentin Accord 400 mg, hard capsules are opaque orange/opaque orange hard gelatin capsules size "0", approximately 21.00 to 21.80 mm long with the imprint "G 400" on the cap in blue ink, containing a white to off-white powder.

The capsules are packed in a PVC/PVdC-aluminum blister pack, aluminum-aluminum blister pack or HDPE bottle.

Package sizes:

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

HDPE bottle: 100 and 500 capsules.

Not all pack sizes mentioned are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Accord Healthcare B.V.

Winthontlaan 200

3526 KV Utrecht

Netherlands

Manufacturer

LABORATORI FUNDACIÓ DAU

C/ C, 12-14 Pol. Ind. Zona Franca,

Barcelona, 08040 Barcelona,

Spain

Accord Healthcare Polska Sp.z o.o.,

ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.

Winthontlaan 200

3526 KV Utrecht

Netherlands

Registered under:

Gabapentin Accord 100 mg, hard capsules RVG 118008

Gabapentin Accord 300 mg, hard capsules RVG 118010

Gabapentin Accord 400 mg, hard capsules RVG 118011

This medicine is registered in EEA member states under the following names:

Name of the member state	Name
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	Gabapentin Accord 100/300/400 mg hard capsules
Malta	Gabapentin 100/300 mg hard capsules
Netherlands	Gabapentin Accord 100/300/400 mg, hard capsules
Norway	Gabapentin Accord
Poland	Gabacol
Sweden	Gabapentin Accord 100/300/400 mg hard capsules

United Kingdom

Gabapentin Accord 100/300/400 mg hard capsules

This leaflet was last approved in March 2025.

Transtoyou