Package leaflet: Information for the patient

Gabapentine Sandoz® 100 mg, capsules, hard
Gabapentine Sandoz® 300 mg, capsules, hard
Gabapentine Sandoz® 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 [Nationally completed name] is and what it is used for
[Nationally completed name] 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 [Nationally completed name] is gabapentin.

[Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name] in addition to the current treatment unless told otherwise. [Nationally completed name] 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 [Nationally completed name]

Do not take [Nationally completed name]
- 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 [Nationally completed name]

- 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 myasthenia gravis (a disease causing muscle weakness) because this medicine may make your symptoms worse
- 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 [Nationally completed name].

Dependence
Some people may become dependent on [Nationally completed name] (a need to keep taking the medicine). They may have withdrawal effects when they stop using [Nationally completed name] or reduce the dose (see section 3, "How to take [Nationally completed name]" and "If you stop taking [Nationally completed name]"). If you have concerns that you may become dependent on [Nationally completed name], it is important that you consult your doctor.

If you notice any of the following signs whilst taking [Nationally completed name], 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 *'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 [Nationally completed name]
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 [Nationally completed name]. In addition, combination of [Nationally completed name] with opioids may cause symptoms like sleepiness, sedation, decrease in breathing, or death.

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

[Nationally completed name]
- is not expected to interact with other antiepileptic medicines 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.

[Nationally completed name] with food
[Nationally completed name] can be taken with or without food.

Pregnancy, breast-feeding and fertility
- If you are pregnant or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the medicine you are taking might pose to your unborn baby.
- You should not stop your treatment without discussing this with your doctor.
- If you are planning to become pregnant you should discuss your treatment with your doctor <or pharmacist> as early as possible before you become pregnant.

- If you are breastfeeding or planning to breastfeed, ask your doctor <or pharmacist> for advice before taking this medicine.

Pregnancy
[Nationally completed name] can be used during the first trimester of pregnancy if needed.
If you plan to become pregnant or if you are pregnant or think you may be pregnant, talk to your doctor straight away.
If you have become pregnant and you have epilepsy, it is important that you do not stop taking your medicine without first consulting your doctor, as this may worsen your illness. Worsening of your epilepsy may put you and your unborn child at risk.
In a study reviewing data from women in Nordic countries who took gabapentin in the first 3 months of pregnancy, there was no increased risk of birth defects or problems with the development of brain function (neurodevelopment disorders). However, babies of women who took gabapentin during pregnancy had an increased risk of low birth weight and preterm birth.

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 [Nationally completed name]. 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 [Nationally completed name], is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using [Nationally completed name].

Fertility
There is no effect on fertility in animal studies.

Driving and using machines
[Nationally completed name] 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 medicine affects your ability to perform these activities.

[Nationally completed name] 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 [Nationally completed name]
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 of body weight 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.

[Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name] is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Method of administration
[Nationally completed name] is for oral use. Always swallow the capsules with plenty of water.

Continue taking [Nationally completed name] until your doctor tells you to stop.

If you take more [Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name]
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 [Nationally completed name]
Do not suddenly stop taking [Nationally completed name] or reduce your dose. If you want to stop taking [Nationally completed name] or reduce your dose, discuss this with your doctor first. They will tell you how to do this. If your treatment is stopped or your dose is reduced, it should be done gradually over a minimum of 1 week. After stopping a short or long-term treatment with [Nationally completed name] or after reducing your dose, 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 [Nationally completed name] or reducing your dose. 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 [Nationally completed name] 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**

- **[Nationally completed name] 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 [Nationally completed name]. Call your doctor right away if you have any of the following symptoms:**

  - **skin rash and redness and/or hair loss**
  - **hives**
  - **fever**
  - **swollen glands that do not go away**
  - **swelling of your lip, face 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 [Nationally completed name].

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

After marketing the following side effects have been reported:

Not known (frequency cannot be estimated from the available data):
- Decreased platelets (blood clotting cells)
- Hallucinations
- Suicidal thoughts
- Problems with abnormal movements such as writhing, jerking movements and stiffness
- Worsening of myasthenia gravis (a disease causing muscle weakness)
- 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 (creatine 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)

- Becoming dependent on [Nationally completed name] (‘drug dependence’)

After stopping a short or long-term treatment with [Nationally completed name] or after reducing your dose, you need to know that you may experience certain side effects, so-called withdrawal effects (see “If you stop taking [Nationally completed name]”).

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 [Nationally completed name]

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 label after ‘EXP’. The expiry date refers to the last day of that month.

Store below 25ºC.
Blisters: Store in the original package in order to protect from moisture.
Bottles: Keep the bottle tightly closed in order to protect from moisture.

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. Content of the pack and other information

What [Nationally completed name] contains
- The active substance is: gabapentin.

[Nationally completed name]
Each capsule, hard contains either 100 mg, 300 mg or 400 mg of gabapentin.

- The other ingredients in the capsules are:
  Capsule content: pregelatinised maize starch, maize starch, talc and colloidal anhydrous silica.
  Capsule shell: consists of gelatin, sodium lauril sulphate, coloured with titanium dioxide (E 171) and iron oxide yellow (E 172) (300 mg and 400 mg capsules) and iron oxide red (E 172) (400 mg capsules).

What [Nationally completed name] looks like and contents of the pack

100 mg capsule, hard:
are gelatin capsules, hard with a white, opaque body and cap.

300 mg capsule, hard:
are gelatin capsules, hard with a yellow, opaque body and cap.

400 mg capsule, hard:

are gelatin capsules, hard with a brown, opaque body and cap.

The hard capsules are packed in PVC/PE/PVDC//Alu blisters or are packed in HDPE bottles with child resistant closure and inserted in a carton.

100 mg capsule, hard:
Blister: 20, 30, 50, 90, 100, 200 and 500 capsules, hard

300 mg capsule, hard:
Blister: 20, 30, 50, 90, 100, 200 and 500 capsules, hard
Bottle: 50, 100 capsules, hard

400 mg capsule, hard:
Blister: 20, 30, 50, 90, 100, 200 and 500 capsules, hard
Bottle: 100 capsules, hard

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

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In het register ingeschreven onder

Gabapentine Sandoz 100 mg, capsules, hard	RVG 33683
Gabapentine Sandoz 300 mg, capsules, hard	RVG 33684
Gabapentine Sandoz 400 mg, capsules, hard	RVG 33685

Dit geneesmiddel is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen

Oostenrijk:	Gabapentin Hexal 100 mg - Kapseln
	Gabapentin Hexal 300 mg - Kapseln
	Gabapentin Hexal 400 mg - Kapseln
Duitsland:	Gabapentin HEXAL 100 mg Hartkapseln
	Gabapentin HEXAL 300 mg Hartkapseln
	Gabapentin HEXAL 400 mg Hartkapseln
Italië:	Gabapentin Hexal A/S 100 mg capsule rigide
	Gabapentin Hexal A/S 300 mg capsule rigide
	Gabapentin Hexal A/S 400 mg capsule rigide
Nederland:	Gabapentine Sandoz 100 mg, capsules, hard
	Gabapentine Sandoz 300 mg, capsules, hard
	Gabapentine Sandoz 400 mg, capsules, hard

Deze bijsluiter is voor het laatst goedgekeurd in april 2026.