

PATIENT INFORMATION LEAFLET
[GABAZIM 300] Gabapentin Capsules USP 300 mg
[Gabapentin USP]

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

- a) What Gabazim 300 is and what it is used for
- b) What you need to know before you take Gabazim 300
- c) How to take Gabazim 300
- d) Possible side effects
- e) How to store Gabazim 300
- f) Contents of the pack and other information

a) What Gabazim 300 is and what it is used for

Gabazim 300 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 Gabazim 300 is gabapentin.

Gabazim 300 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 Gabazim 300 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 Gabazim 300 in addition to the current treatment unless told otherwise. Gabazim 300 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.

b) What you need to know before you take Gabazim 300 Do not take Gabazim 300:

- 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 Gabazim 300

- 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 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 Gabazim 300

Dependence

Some people may become dependent on Gabazim 300 (a need to keep taking the medicine). They may have withdrawal effects when they stop using Gabazim 300 (see section 3, “How to take Gabazim 300” and “If you stop taking Gabazim 300”). If you have concerns that you may become dependent on Gabazim 300, it is important that you consult your doctor.

If you notice any of the following signs whilst taking Gabazim 300, 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 serious 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 Gabazim 300

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 Gabazim 300. In addition, combination of Gabazim 300 with opioids may cause sleepiness, sedation, decrease in breathing, or death.

Antacids for indigestion

If Gabazim 300 and antacids containing aluminium and magnesium are taken at the same time, absorption of Gabazim 300 from the stomach may be reduced. It is therefore recommended that Gabazim 300 is taken at the earliest two hours after taking an antacid.

Gabazim 300

- 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.

Gabazim 300 with food

Gabazim 300 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

Gabazim 300 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 Gabazim 300. 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 Gabazim 300, is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using Gabazim 300.

Fertility

There is no effect on fertility in animal studies.

Driving and using machines

Gabazim 300 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.

Gabazim 300 contains lactose

Gabazim 300 hard 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.

Gabazim 300 contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 100 mg, 300 mg and 400 mg hard capsules, that is to say essentially 'sodium-free'.

c) How to take Gabazim 300

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 or tablets 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) or tablet(s) each day, usually once in the morning, once in the afternoon and once in the evening.

Gabazim 300 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 or tablets 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 Gabazim 300 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 Gabazim 300 is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Method of administration

Gabazim 300 is for oral use. Always swallow the capsules or tablets with plenty of water. The tablet can be divided into equal halves.

Continue taking Gabazim 300 until your doctor tells you to stop.

If you take more Gabazim 300 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 Gabazim 300 than your doctor prescribed. Take along any capsules or tablets 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 Gabazim 300

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 Gabazim 300

Do not suddenly stop taking Gabazim 300. If you want to stop taking Gabazim 300, 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 Gabazim 300, 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 Gabazim 300. 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.

d) Possible side effects

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

Stop using Gabazim 300 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:

- 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
- Gabazim 300 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 Gabazim 300. 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 Gabazim 300.

- 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
- Difficulty swallowing
- 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)

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 Gabazim 300 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 (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 Gabazim 300 ('drug dependence')

After stopping a short or long-term treatment with Gabazim 300, you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking Gabazim 300").

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.

e) How to store Gabazim 300

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store at a temperature not exceeding 30°C, protect from moisture. Keep out of the reach of children 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.

f) Contents of the pack and other information

What Gabazim 300 contains: The active substance - Gabapentin

Composition: Each Hard Gelatin Capsule contains:

Gabapentin USP 300 mg

The other ingredients are:

Microcrystalline Cellulose

Colloidal anhydrous Silica

Purified talc

Magnesium stearate

What Gabazim 300 looks like and contents of the pack

Gabazim 300 is Size "1" hard gelatin capsule with blue colour body and blue colour cap, filled with white powder.

Gabazim 300 packed in Alu PVC blister pack of 10 tablets. Such 1 blister packed in carton along with pack insert.

Marketing Authorisation Holder and Manufacturer

ZIM Laboratories Limited

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For any information about this medicinal product, please contact the local representative of the supplier:

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This Leaflet was last approved in {01/2024}