

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gabapentin Glenmark 50 mg/ml Oral Solution

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, 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 possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Gabapentin Oral Solution is and what it is used for
2. What you need to know before you take Gabapentin Oral Solution
3. How to take Gabapentin Oral Solution
4. Possible side effects
5. How to store Gabapentin Oral Solution
6. Contents of the pack and other information

1. WHAT GABAPENTIN ORAL SOLUTION IS AND WHAT IT IS USED FOR

Gabapentin Glenmark 50 mg/ml Oral Solution (referred to in this leaflet as Gabapentin Oral Solution) contains the active ingredient gabapentin. It belongs to a group of medicines used **to treat epilepsy and peripheral neuropathic pain** (long lasting pain caused by damage to the nerves).

For epilepsy:

- It is used for 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 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.

For peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

- A variety of different diseases, such as diabetes or shingles, can cause peripheral neuropathic pain (primarily occurring in the legs and/or arms). 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 ORAL SOLUTION

Do not take Gabapentin Oral Solution 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
- 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
- if you have a **history of abuse or dependence**.
- 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 Oral Solution.

Dependence

Some people may become dependent on Gabapentin Oral Solution (a need to keep taking the medicine).

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

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

Important Information about potentially serious reactions

- A small number of people taking epilepsy medicines like Gabapentin have had thoughts of **harming or killing themselves**. If at any time you have these thoughts, talk to your doctor straight away.
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 creatinine 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 recently taken any medicines for **convulsions, sleeping disorders, depression, anxiety**, or any other **neurological or psychiatric problems**.

Gabapentin is not expected to interact with other antiepileptic drugs or the oral contraceptive pill. Gabapentin may interfere with some laboratory tests. If you require a urine test, tell your doctor or the hospital staff that you are taking Gabapentin.

Medicines containing opioids such as morphine

Tell your doctor or pharmacist if you are taking medicines containing opioids (such as morphine) 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, the 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 with food

Gabapentin 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

Contact your doctor immediately if you become pregnant or think you might be pregnant while taking Gabapentin.

Gabapentin Oral Solution 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).

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 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 cause **dizziness, drowsiness** and **tiredness**. You should not drive, operate machinery or take part in other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

Gabapentin Oral Solution contains

- Methyl parahydroxybenzoate (E218) and Ethyl parahydroxybenzoate (E214). These may cause allergic reactions (possibly delayed).
- Potassium – 2.37 mg per 1ml dose. This should be taken into consideration for patients with reduced kidney function or patients on controlled potassium diets.
- Sodium – This medicine contains less than 1 mmol sodium (23 mg) per dose (300 mg gabapentin), that is to say essentially ‘sodium-free’.
- Propylene glycol (43 mg in a 1 ml dose) – if you are pregnant, breast-feeding or suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.
- Benzyl alcohol – 0.04 mg per 1 ml dose. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have a liver or kidney disease, if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called ‘metabolic acidosis’).

3. HOW TO TAKE GABAPENTIN ORAL SOLUTION

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. This will depend on how well your body responds to this medicine.

How and when to take Gabapentin Oral Solution

Gabapentin is for oral use and should be taken with plenty of water.

It is usually given in **3 separate doses**, i.e. once in the **morning**, once in the **afternoon** and once in the **evening**.

Continue taking Gabapentin until your doctor tells you to stop.

Epilepsy:

Adults and adolescents

The starting dose will generally be between 300 mg and 900 mg each day (6 to 18 ml). Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3600 mg each day (72 ml)

Children aged 6 years old 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. Gabapentin is not recommended for use in children under 6 years old.

Peripheral neuropathic pain:

Adults

The starting dose will generally be between 300 mg and 900 mg each day (6 to 18 ml). Thereafter, the dose may be increased as instructed by your doctor up to a maximum of 3600 mg each day (72 ml).

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)

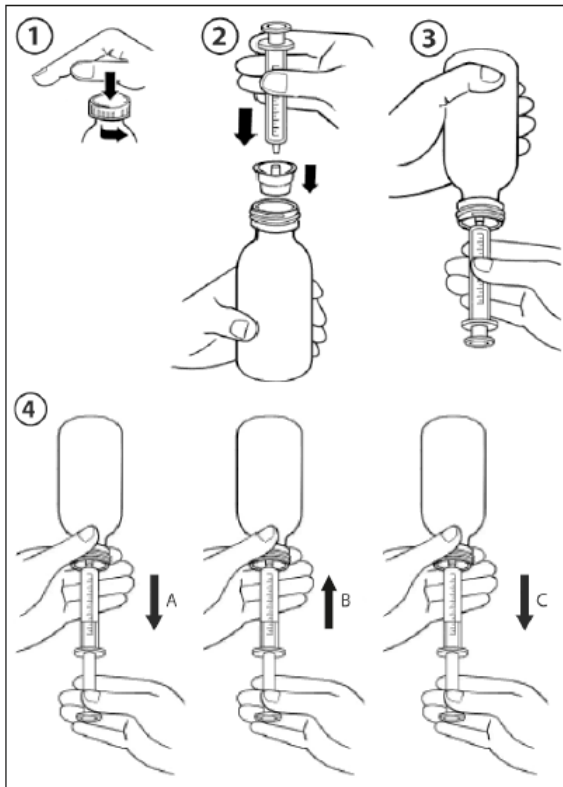
You should take the normal dose of Gabapentin unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

If you think that the effect of Gabapentin is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Measuring your dose using the oral syringe provided

Your pack contains a plastic oral syringe to measure the right amount of liquid prescribed for you. The numbers up the side show how many millilitres (ml) of liquid you have inside the syringe.

1. Open the bottle: press the cap and turn it anticlockwise (figure 1).
2. Insert the syringe adaptor into the bottle neck (figure 2).
3. Take the syringe and put it in the adaptor opening (figure 2).
4. Turn the bottle upside down (figure 3).
5. Fill the syringe with a small amount of solution by pulling the piston down (figure 4A).
6. Push the piston upward in order to remove any possible bubbles (figure 4B).
7. Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 4C).
8. Turn the bottle the right way up.
9. Remove the syringe from the adaptor. Put the end of the syringe into your mouth and push the piston slowly back in to take the medicine.
10. Wash the syringe with water and let it dry before you use it again.
11. Close the bottle with the plastic screw cap.



If you take more Gabapentin than you should

- Call your doctor or go to the nearest hospital emergency unit immediately if you take more Gabapentin than you should. Take the medicine pack with you.
- Higher than recommended doses may result in an increase in side effects including loss of consciousness, dizziness, double vision, slurred speech, drowsiness and diarrhoea.

If you forget to take Gabapentin

- If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed 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 Oral Solution. If you want to stop taking Gabapentin Oral Solution, discuss this with your doctor first. They will tell you how to do this.
- If your treatment needs to be stopped, it should be done gradually over a minimum of a week.
- After stopping a short or long-term treatment with Gabapentin Oral Solution, 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 Oral Solution. 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

Stop using Gabapentin Oral Solution 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).

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

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
- 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 immediately 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 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 infection, urinary tract infections, 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
- Difficulty 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 reactions 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 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 fibres (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 Gabapentin Oral Solution ('drug dependence')

After stopping a short or long-term treatment with Gabapentin Oral Solution, you need to know that

you may experience certain side effects, so-called withdrawal effects (see “If you stop taking Gabapentin Oral Solution).

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 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 ORAL SOLUTION

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not freeze.
- Store in the original bottle in order to protect from light.
- Do not use 1 month after you first open it.
- Do not use after the expiry date (month, year) stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Do not use Gabapentin if you notice anything wrong with the medicine. Talk to your pharmacist.
- 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. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What Gabapentin Oral Solution contains:

- The active substance is gabapentin. Each 1 ml contains 50 mg gabapentin.
- The other ingredients are acesulfame potassium (E950), saccharin sodium (E954), propylene glycol (E1520), methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), carmellose sodium (E466), tutti frutti flavour (containing benzyl alcohol) and purified water.

What Gabapentin Oral Solution looks like and contents of the pack

Gabapentin is a clear, colourless oral solution. It comes in an amber coloured glass bottle as well as in an amber coloured polyethylene terephthalate bottle holding 150 ml of solution.

In the pack there is also a 10 ml oral syringe, with markings at every 1ml and intermediate marks at every 0.5 ml.

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Information for Healthcare Professionals

Administration via NG or PEG tubes

The minimum volume of water that is required to flush is 5mL.

1. Ensure the tube is clear before taking the medicine.
2. Flush the tube with the minimum volume of water required.
3. Administer the medicine into the tube with a suitable measuring device. The syringe included in the pack is only for patients who are able to swallow the medicine. HCPs administering this product to patients via a NG or PEG tube must use another suitable device.
4. Flush the tube again with the minimum volume of water.

For use with silicone, PVC and polyurethane NG or PEG tubes **only**.