

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** 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**.

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.
- A small number of people taking Gabapentin get an **allergic reaction** or potentially **serious skin reaction**, which may develop into more serious problems if they are not treated. You need to know these symptoms to look out for while you are taking Gabapentin. Read the description of these symptoms in section 4 of this leaflet under '*Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious*'.
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**, 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. 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 (fits), 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) for treating pain. This is because morphine may increase the effect of Gabapentin. You may also have symptoms such as sleepiness and/or decrease in breathing.

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 and drink

Gabapentin can be taken with or without food.

Pregnancy, breast-feeding and fertility

Pregnancy

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

Gabapentin **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 medicines used to treat seizures have reported an increased risk of harm to the developing baby, particularly when more than one seizure medicine is taken at the same time. Therefore, whenever possible, you should try to take only one seizure medicine during pregnancy and only under the advice of your doctor.

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 you.

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. 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)

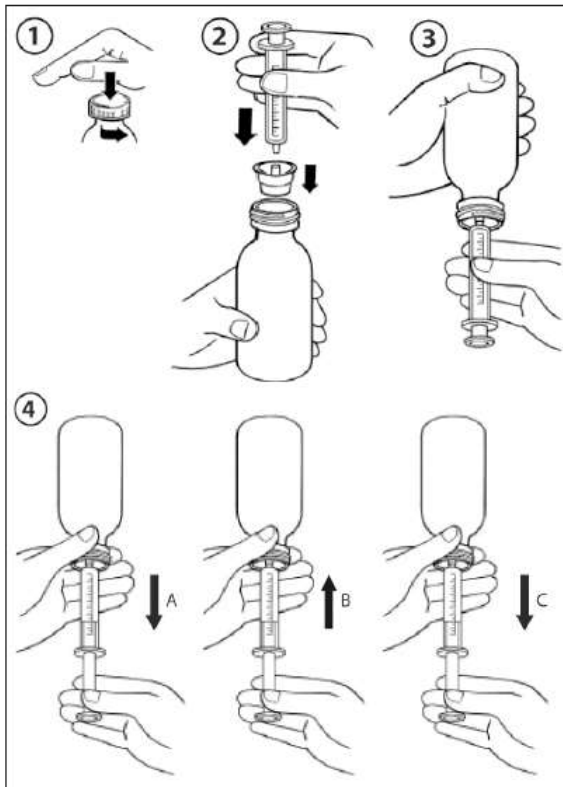
You should take the normal dose of Gabapentin unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

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 stop taking Gabapentin unless your doctor tells you to.
- If your treatment needs to be stopped, it should be done gradually over a minimum of a week.
- If you stop taking Gabapentin suddenly or before your doctor tells you, there is an increased risk of seizures (fits).

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 everyone gets them. The following side effects may happen with this medicine:

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
- 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
 - hives
 - fever
 - swollen glands that do not go away
 - swelling of your lip 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 your 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
- Facial swelling, bruises, rash, itch, acne
- Difficulty with erection (impotence)
- Swelling in your legs and arms, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
- Decrease in your 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
- 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)
- Hallucinations
- Problems with abnormal movements such as writhing, jerking movements and stiffness.
- Ringing in the ears
- A group of side effects that could include swollen lymph nodes (isolated small raised lumps under the skin), fever, rash and inflammation of your liver occurring together
- Yellowing of the skin and eyes (jaundice), inflammation of the liver
- Acute kidney failure, incontinence
- Increased breast tissue, breast enlargement
- Adverse events following the abrupt discontinuation of gabapentin (anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
- Breakdown of muscle fibres (rhabdomyolysis)
- Change in blood test results (creatinine phosphokinase increased)
- Problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation
- Low blood sodium level.
- Anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat and tongue and hypotension requiring emergency treatment).

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard 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.

Marketing Authorisation Holder

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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**.