Package leaflet: Information for the user

Neurisol 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 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 <invented name> is and what it is used for

<invented name> contains the active substance gabapentin which belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

<invented 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 will prescribe <invented name> to help treat epilepsy when the current treatment is not fully controlling the condition. Adults and children aged 6 years and above should take <invented name> in addition to the current treatment unless told otherwise.
  <invented name> can also be used on its own to treat adults and adolescents aged 12 years and above.

- 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 <invented name>

Do not take <invented name>
- 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 <invented name>:

- if you have 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 myasthenia gravis (a disease causing muscle weakness) because this medicine may make your symptoms worse
- 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 <invented name>.

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.

Dependence
Some people may become dependent on <invented name> (a need to keep taking the medicine). They may have withdrawal effects when they stop using <invented name> or reduce the dose (see section 3, "How to take <invented name>" and "If you stop taking <invented name>"). If you have concerns that you may become dependent on <invented name>, it is important that you consult your doctor.
If you notice any of the following signs whilst taking <invented 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.

Cases of abuse and dependence have been reported for gabapentin after marketing. Talk to your doctor if you have a history of abuse or dependence.

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 "Stop using <invented name> and seek medical attention immediately if you notice any of the following symptoms" and "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 <invented 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 <invented name>. In addition, combination of <invented name> with opioids may cause sleepiness, sedation, decrease in breathing, and be life-threatening.

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

<invented 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.

<invented name> with food
<invented name> can be taken with or without food.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
<invented name> can be used during the first 3 months of pregnancy if needed.

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.

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 (medicines for treatment of severe pain). Newborns should be monitored carefully by the healthcare professionals.

Breast-feeding
Gabapentin, the active substance of <invented name>, is passed on through human milk. Because the effect on the baby is unknown, this medicine should only be used in breast-feeding women if the benefits clearly outweigh the risks.

Driving and using machines
<invented 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 medication affects your ability to perform these activities.

<Invented name> contains sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, propylene glycol and benzyl alcohol

Sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

This medicine contains 43 mg propylene glycol in each 1 ml of oral solution.
If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
If you 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.

This medicine contains 0.08 mg benzyl alcohol in each 1 ml of oral solution.

Benzyl alcohol may cause allergic reactions.
Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children.
Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

This medicine contains less than 1 mmol sodium (23 mg) per 24 ml of oral solution, that is to say essentially ‘sodium-free’.

3. How to take <invented 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. For doses not practicable with this medicine, other pharmaceutical forms and products are available.

Epilepsy, the recommended dose is:

Adults and adolescents aged 12 years and above
Your doctor will usually build up your dose gradually. The starting dose will generally be between 6 ml (300 mg) and 18 ml (900 mg) each day. Thereafter, the dose may be increased as instructed by your doctor up to a maximum of 72 ml (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 0.5-0.7 ml (25-35 mg) per kg per day. It is usually given in 3 separate doses, usually once in the morning, once in the afternoon and once in the evening.

Children under 6 years
<invented name> is not recommended for use in children below 6 years of age.

Peripheral Neuropathic Pain, the recommended dose is:
Adults
Your doctor will usually build up your dose gradually. The starting dose will generally be between 6 ml (300 mg) and 18 ml (900 mg) each day. Thereafter, the dose may be increased as instructed by your doctor up to a maximum of 72 ml (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 <invented 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.

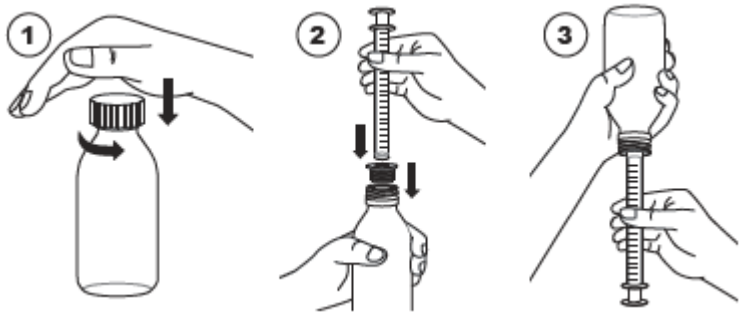
If you have the impression that the effect of <invented name> is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Method of administration

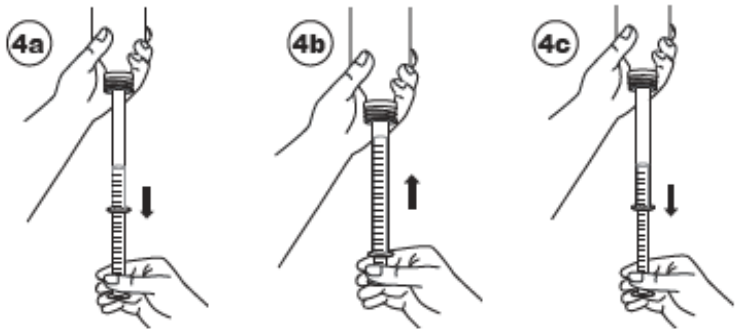
This medicine must be taken orally.
A 10 ml oral syringe, with 0.5 ml graduation, is included in the carton together with a press-in bottle adaptor for the syringe. Use these to measure the required dose. <invented name> can be taken with or without food.

How to give this medicine:

1. Open the bottle: press the cap and turn it anticlockwise (figure 1).
2. At first use, insert the press-in bottle adaptor into the bottle neck (figure 2). Ensure it is properly fixed. The adaptor connects the oral syringe to the bottle and remains in the bottle neck.
3. Put the syringe in the adaptor opening (figure 2).
4. Turn the bottle upside down (figure 3).



Fill the syringe with a small amount of solution by pulling the plunger down (figure 4A). Push the plunger upwards to remove any possible bubbles (figure 4B). Pull the plunger down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 4C).



5. Turn the bottle back to the upright position and remove the syringe from the adaptor.
6. Empty the contents of the syringe into the patient's mouth by pushing the plunger to the bottom of the syringe.
7. For higher dose, repeat step 3 to 6.
8. Close the bottle with the plastic screw cap (adaptor remains in place). Wash the syringe on the out- and inside with water and let it dry before you use it again.

If you are giving <invented name> to a child:

- Make sure that the child is sitting up or standing.
- Put the syringe into the child's mouth, placing the syringe-opening in the area between the gums and the inside of the cheek.
- Push the plunger slowly, giving the child time to swallow the medicine.
- Give the child some water to drink in order to ensure that all the medicine is washed down.

Alternative method of administration (with feeding tubes)
This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. Ask your doctor, pharmacist or nurse about this if the medicine cannot be swallowed.

Administering this medicine via NG or PEG tube:
Only use **polyurethane** NG or PEG tubes.
1. Ensure the tube is clear before administering the medicine.
2. Flush the tube with 10 ml of boiled cooled water.
3. Administer the medicine into the tube with a suitable measuring device.
4. Immediately, flush the tube again, twice, with 10 ml of boiled cooled water.

If you take more <invented 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 <invented name> than your doctor prescribed. If possible take this medicine pack with you to show them what you have taken.

If you forget to take <invented 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 <invented name>
Do not suddenly stop taking <invented name> or reduce your dose unless you experience any of the skin reactions described in section 4.
If you want to stop taking <invented 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 <invented 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 <invented 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 <invented 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)
- serious, potentially life-threatening allergic reaction including low blood pressure, difficulty breathing, swelling of the lips, throat and tongue, and requiring emergency treatment (anaphylaxis)

- 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
- <invented 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 <invented 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 <invented 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
- 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 <invented name> 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
- Worsening of myasthenia gravis (a disease causing muscle weakness)

Not known (cannot be estimated from the available data)
- becoming dependent on <invented name> (“drug dependence”)

After stopping a short or long-term treatment with <invented 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 <invented name>”).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. 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 <invented 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 carton and label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
After first opening do not store above 25°C and use within 1 month.

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 pack and other information

What <invented name> contains

- The active substance is gabapentin; each ml of solution contains 50 mg of gabapentin.
- The other ingredients are: sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), propylene glycol (E1520), carmellose sodium (E466), acesulfame potassium (E950), orange flavour (including propylene glycol and benzyl alcohol), hydrochloric acid, concentrated (for pH adjustment), and purified water.

What <invented name> looks like and contents of the pack

<invented name> is a clear, colourless solution with characteristic orange odour. It is supplied in amber, type III glass bottle with a child-resistant and tamper evident screw cap.

A plastic 10 ml graduated oral syringe with intermediate graduations of 0.5 ml and a plastic “press-in” syringe/bottle adapter are also provided in the carton.

Pack size of 150 ml is available.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in

2026-01-15