

Package Leaflet: Information for the User

Gabapentin Rosemont 50mg/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 Gabapentin Rosemont is and what it is used for
2. What you need to know before you take Gabapentin Rosemont
3. How to take Gabapentin Rosemont
4. Possible side effects
5. How to store Gabapentin Rosemont
6. Contents of the pack and other information

1. What Gabapentin Rosemont is and what it is used for

The name of your medicine is Gabapentin Rosemont 50mg/ml Oral Solution (called Gabapentin in this leaflet). Gabapentin 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:

- 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). Your doctor will prescribe Gabapentin for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Gabapentin in addition to your 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 can cause peripheral (primarily occurring in the legs and/or arms) neuropathic pain, 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 Gabapentin Rosemont

Do not take this medicine if:

- you are allergic (hypersensitive) to gabapentin or any of the other ingredients (listed in Section 6). An allergic reaction can include a rash, itching or shortness of breath.

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.

Cases of abuse and dependence have been reported for gabapentin from the post-marketing experience. Talk to your doctor if you have a history of abuse or dependence.

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.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Gabapentin.

Important Information about potentially serious reactions

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’.

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 Gabapentin

Please tell your doctor or pharmacist if you are taking or have recently taken 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. This includes medicines obtained without a prescription, including herbal medicines. This is

because Gabapentin can affect the way some other medicines work. Also some other medicines can affect the way Gabapentin works.

Medicines containing opioids such as morphine

In particular tell your doctor or pharmacist if you are taking medicines containing opioids (such as morphine), used for pain. This is because morphine may increase the effect of Gabapentin. In addition, combination of Gabapentin with opioids may cause symptoms like sleepiness and/or decrease in breathing.

Antacids for indigestion

If Gabapentin and antacids containing aluminium and magnesium are taken at the same time, 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 does not normally affect other medicines for epilepsy or the oral contraceptive pill.

Gabapentin may interfere with some laboratory tests, if you require a urine test tell your doctor or hospital that you are taking Gabapentin.

Gabapentin with food and drink

Gabapentin can be taken with or without food.

Pregnancy, breast-feeding and fertility

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

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 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.

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

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Gabapentin 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.

Gabapentin Rosemont contains methyl and ethyl parahydroxybenzoates, potassium, sodium and propylene glycol:

- methyl and ethyl parahydroxybenzoates - these may cause an allergic reaction which may happen some time after starting the medicine
- potassium (3.8mg in a 1ml dose) - if you have kidney problems or are on a low potassium diet, you need to take this into account
- sodium (0.72mg in 1ml dose) - (main component of cooking/table salt) this is equivalent to 0.04% of the recommended maximum daily dietary intake of sodium for an adult. If you are on a low sodium diet, you need to take this into account
- propylene glycol (35mg in a 1ml 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.

3. How to take Gabapentin Rosemont

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Gabapentin Rosemont Oral Solution contains 50mg of gabapentin in each 1ml. Your doctor will determine what dose is appropriate for you.

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

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.

Continue taking Gabapentin until your doctor tells you to stop.

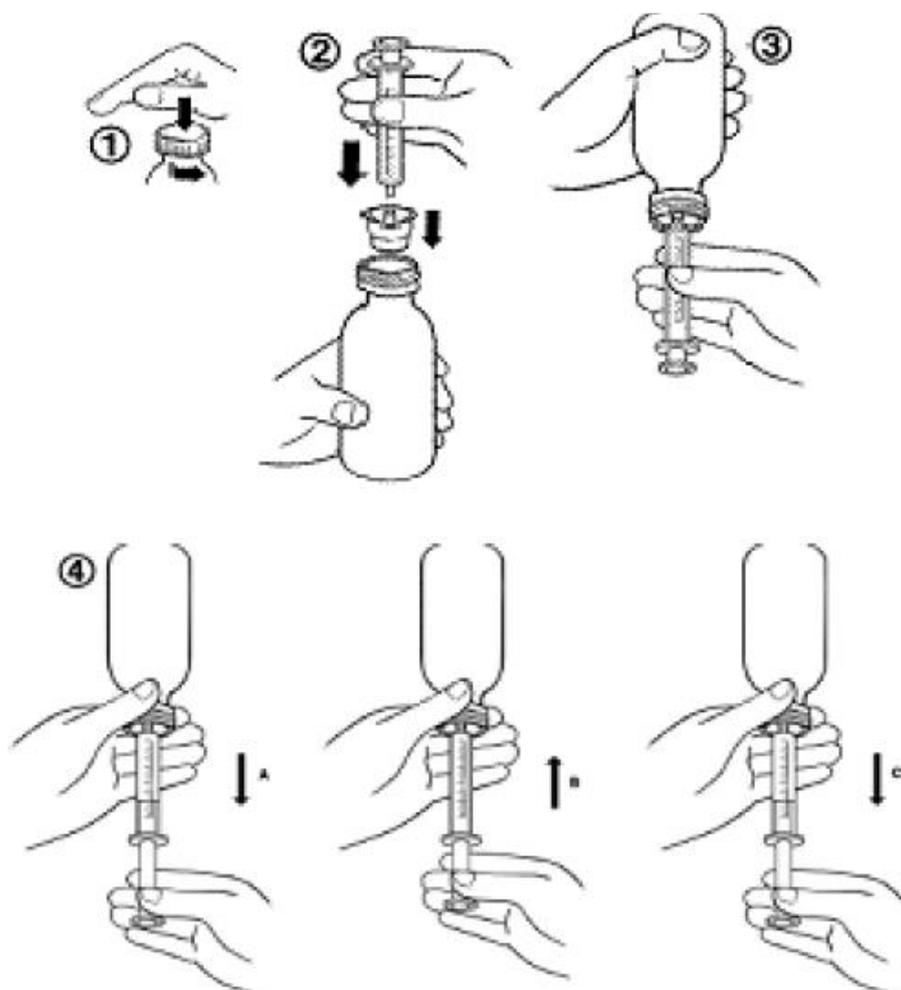
Method and route of administration

Gabapentin is for oral use.

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 (mls) 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). Then push the piston upward in order to remove any possible bubbles (figure 4B). Finally, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 4C).
6. Turn the bottle the right way up.
7. 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.
8. Wash the syringe with water and let it dry before you use it again.
9. Close the bottle with the plastic screw cap.



This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes only. There is further information in the SmPC, ask your doctor, pharmacist or nurse for this information.

Taking this medicine via NG or PEG tubes

The minimum volume of water that is required to flush tube sizes 8 Fr and below is 5mL and for tube sizes 10 Fr and above it is 10mL.

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**.

For epilepsy:

Adults and young people over 12 years old

- The usual starting dose is between 300mg and 900mg a day (6 to 18ml).
- This will be increased gradually by your doctor.
- The maximum dose is 3,600mg a day (72ml).
- Take the medicine in three separate doses: once in the morning, once in the afternoon and once in the evening.

Children aged 6 years old and above

- The doctor will decide the dose, depending on your child's weight.
- The treatment is started with a low starting dose which is gradually increased over about three days.
- The usual dose is 25 to 35mg for each kilogram of body weight a day.
- It is usually given in three separate doses: once in the morning, once in the afternoon and once in the evening.

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

For peripheral neuropathic pain:

Adults

- The usual starting dose is between 300mg and 900mg a day (6 to 18ml).
- This will be increased gradually by your doctor.
- The maximum dose is 3,600mg a day (72ml).
- Take the medicine in three separate doses: 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 feel that the effect of Gabapentin is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

If you take more Gabapentin 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 Gabapentin than you should. Take the medicine pack with you.

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Gabapentin can cause side effects, although not everybody 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:

Common side-effects (affects less than 1 in 10 people):

- convulsions/fits
- pneumonia, respiratory infections
- breathing problems, which if severe you may need emergency and intensive care to continue breathing normally.

Rare (may affect up to 1 in 1,000 people):

- loss of consciousness.

Not known (frequency cannot be estimated from the available data):

- Gabapentin may cause a “serious, potentially life-threatening allergic reaction (anaphylaxis) including difficulty breathing, swelling of the lips, throat and tongue, and hypotension requiring emergency treatment”. You may or may not have a rash when you get this type of reaction. It may cause you to be hospitalized or to stop Gabapentin.
- persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas)
- skin rash, hives, fever, swollen glands that do not go away, swelling of your lip and tongue
- yellowing of your skin or the whites of the eyes
- unusual bruising or bleeding, severe fatigue or weakness
- unexpected muscle pain
- signs of frequent infections such as fever, flu like symptoms and sore throat
- ringing in the ears

- problems with abnormal movements such as writhing, jerking movements and stiffness.

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 side-effects (affects more than 1 in 10 people):

- viral infection
- feeling drowsy, dizziness, lack of coordination
- feeling tired, fever.

Common side-effects (affects less than 1 in 10 people):

- 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
- jerky movements, difficulty 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
- 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 side effects (affects less than 1 in 100 people):

- 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)
- agitation (a state of chronic restlessness and unintentional and purposeless motions)
- difficulty swallowing.

Rare (may affect up to 1 in 1,000 people):

- decrease in blood glucose levels (most often observed in patients with diabetes)
- trouble breathing, shallow breaths (respiratory depression).

Not known (frequency cannot be estimated from the available data):

- decreased platelets (blood clotting cells)
- hallucinations
- 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
- 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
- blood glucose fluctuations in patients with diabetes
- 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

5. How to store Gabapentin Rosemont

- Keep out of the sight and reach of children.
- Do not store above 25°C. Do not refrigerate or freeze.
- 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 pack and other information

What Gabapentin contains

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

What Gabapentin looks like and contents of the pack

Gabapentin is a clear, colourless oral solution. It comes in a brown glass bottle holding 150ml of solution. In the pack there is also a 10ml oral syringe, with markings at every 1ml and intermediate marks at every 0.5ml.

Marketing Authorisation Holder

Taw Pharma (Ireland) Ltd
104 Lower Baggot Street,
Dublin 2, D02 Y940,
Ireland

Manufacturer

Jenson R+ (Ireland) Ltd, 2 Dublin Landing, N Wall Quay, North Dock, Dublin 1, D01 V4A3, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Gabapentin Rosemont 50mg/ml Oral Solution
United Kingdom	Gabapentin Rosemont 50mg/ml Oral Solution

This leaflet was last revised in 02/2021.