

Gabapentin Colonis 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

- What Gabapentin Oral Solution is and what it is used for
- What you need to know before you take Gabapentin Oral Solution
- How to take Gabapentin Oral Solution
- Possible side effects
- How to store Gabapentin Oral Solution
- Contents of the pack and other information

1. What Gabapentin Oral Solution is and what it is used for

Gabapentin Colonis 50mg/ml Oral Solution (referred to in this leaflet as Gabapentin Oral Solution) contains the active ingredient gabapentin. It belongs to a group of medicines called antiepileptics.

Gabapentin Oral Solution 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 Oral Solution for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take this medicine in addition to your current treatment unless told otherwise. Gabapentin Oral Solution can also be used on its own to treat adults and children over 12 years of age.
- Long lasting pain caused by damage to the nerves**, (known as peripheral neuropathic pain). A variety of different diseases such as diabetes or shingles can cause peripheral neuropathic pain (which primarily occurs 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 Oral Solution:

- if you suffer from **kidney problems** your doctor may prescribe a different dosing schedule.
- if you have a **history of abuse or dependence**, cases of abuse and dependence have been reported for gabapentin from the post-marketing experience.
- 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.

Important information about potentially serious reactions

- 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).
- 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 the symptoms to look out for while you are taking Gabapentin Oral Solution**, which are listed in section 4. Side effects under *Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious.*
- If you experience any of the following signs or symptoms, please **contact your doctor immediately**: **Muscle weakness, tenderness or pain** and particularly, if at the **same time, you feel unwell or have a high temperature** because it may be caused by an abnormal muscle breakdown which can be **life-threatening and lead to kidney problems**. You may also experience **discolouration** of your **urine**, and a change in **blood test results** (notably blood creatine phosphokinase increased).
- If you have thoughts of **harming or killing yourself**: A small number of people being treated with antiepileptics such as this medicine have had suicidal thoughts. If at any time you have these thoughts, **contact your doctor immediately**.

Laboratory Tests

- If you require a **urine test** tell your **doctor or hospital** you are taking this medicine because it may affect some **laboratory test results**.

Children

Gabapentin Oral Solution is not recommended for use in children **under 6 years** of age.

Other medicines and Gabapentin Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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.

In particular you must **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** because they can increase the effect of gabapentin and may cause symptoms like sleepiness and/or a decrease in breathing.
- Antacids for indigestion** because if the antacids contain aluminium or magnesium and are taken at the same time, absorption of gabapentin from the stomach may be reduced making it less effective. It is therefore recommended that Gabapentin Oral Solution is taken at **least two hours after taking an antacid**.

Gabapentin Oral Solution does not normally affect:

- the oral contraceptive pill.

Gabapentin Oral Solution with food

Gabapentin Oral Solution 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 Oral Solution 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 medicine to control seizures 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 this medicine.
- Do not suddenly stop taking this medicine** as this may lead to a breakthrough seizure, which could have serious consequences for you and your baby.

Breast-feeding

The active ingredient in this medicine, gabapentin, is passed into breast milk. **Breast-feeding is not recommended** while you are taking Gabapentin Oral Solution because the effect on the baby is unknown.

Fertility

There is no effect on fertility in animal studies.

Driving and using machines

- Gabapentin Oral Solution **can make you feel dizzy, drowsy and tired**, especially when you start this treatment or if your dose is increased.
- You should not drive, operate complex machinery or take part in other potentially hazardous activities until you know whether this medicine affects your ability to carry out these activities safely.
- If you experience side effects which may affect your ability to do these activities safely, then **do not drive or operate machinery until the effects have completely disappeared**.

Gabapentin Oral Solution contains:

- parahydroxybenzoates which may cause **allergic reactions** (possibly delayed)
- small amounts of ethanol (**alcohol**), less than 100mg per ml.

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 the dose which is appropriate for you. This will depend on how well your body responds to this medicine.

Epilepsy, the recommended dose is:

Adults and adolescents:

- Your doctor will usually build up your dose gradually.
- The **starting dose** will generally be between 6ml (300mg) and 18ml (900mg) each day.
- Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 72ml (3600mg) 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 to 12 years old:

- The dose to be given to your child will be decided by your doctor as it is calculated using 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 25–35mg per kg of body weight per day. It is usually given in **3 separate doses**, usually once in the **morning**, once in the **afternoon** and once in the **evening**.

Peripheral Neuropathic Pain, the recommended dose is:

Adults:

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

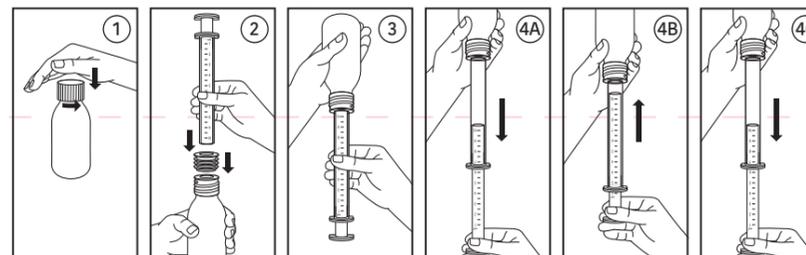
If you are an **elderly patient (over 65 years of age)**, you should take the normal dose of Gabapentin Oral Solution unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

If you think that this medicine is either not working as well as it should be or the effect is too strong talk to your doctor or pharmacist as soon as possible.

Directions for use

- This medicine is for oral use.
- Once the bottle is opened, **use within 1 month**.
- Your pack contains a plastic syringe to measure the right amount of liquid prescribed for you. The numbers up to 10 on the side show how many millilitres (mls) of liquid you have inside the syringe.

- Open the bottle, press the cap and turn it anticlockwise (figure 1).
- Insert the syringe adaptor into the bottle neck (figure 2).
- Take the syringe and put it in the adaptor opening (figure 2).
- Turn the bottle upside down (figure 3).
- 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 ml prescribed by your doctor (figure 4C).
- Turn the bottle the right way up.
- 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.
- Repeat steps 3 to 7 if necessary to take the full dose prescribed by your doctor.
- Wash the syringe with water and let it dry before you use it again.
- Close the bottle with the plastic screw cap.



Alternative method of administration (with feeding tubes)

This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. If you want to know more, there is information in the Summary of Product Characteristics (SmPC). Ask your doctor, pharmacist or nurse about this.

Administering this medicine via NG or PEG tubes

Only use polyurethane NG or PEG tubes.

1. Ensure the tube is clear before administering the medicine.
2. Flush the tube with 10ml of boiled cooled water.
3. Administer the medicine into the tube with a suitable measuring device.
4. Immediately, flush the tube again, twice, with 10ml of boiled cooled water.

If you take more Gabapentin Oral Solution 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.
- **Seek medical advice** or go to the nearest hospital emergency unit **immediately** if you take more Gabapentin Oral Solution than your doctor has prescribed. If possible take this medicine pack with you to show them what you have taken.

If you forget to take Gabapentin Oral Solution

- 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 Gabapentin Oral Solution

- **Do not stop taking this medicine unless your doctor tells you to.**
- If your treatment is stopped it should be done gradually over a **minimum of 1 week**.
- If you **stop** taking Gabapentin Oral Solution **suddenly** or before your doctor tells you, there is an increased risk of **having 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, this medicine can cause side effects, although not everybody gets them.

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 or being **sick** as these may be symptoms of acute pancreatitis (an inflamed pancreas).
- 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 a **rash** when you get this type of reaction. It may cause you to be **hospitalized or to stop taking this medicine**. Call your **doctor right away** 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.
- **Breathing problems**, which if **severe you may need emergency and intensive care** to continue breathing normally.

These symptoms may be the first signs of a serious reaction. A doctor should examine you to decide if you should continue taking Gabapentin Oral Solution.

- If you are on **haemodialysis**, tell your doctor if you develop **muscle pain and/or weakness**.

Other side effects include:

Very common (affects more than 1 in 10 people):

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

Common (affects up to 1 in 10 people):

- pneumonia, respiratory infections, urinary tract infection, inflammation of the ear or other infections
- low white blood cell counts or a reduction in white blood cells
- anorexia or 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 e.g. "pins and needles" sensation, decreased sensation (numbness), difficulty with coordination, unusual eye movement, increased, decreased or absent reflexes
- blurred vision, double vision
- vertigo (a feeling of spinning)
- high blood pressure, flushing or dilation of blood vessels
- difficulty breathing, bronchitis, sore throat, cough, dry nose
- feeling or being sick, diarrhoea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
- problems with your teeth or inflamed gums
- 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, feeling weak, pain, feeling unwell, flu-like symptoms
- increase in weight
- accidental injury, fracture, abrasion.

Additionally in clinical studies in children, aggressive behaviour and jerky movements were commonly reported.

Uncommon (affects up to 1 in 100 people):

- allergic reaction such as hives
- decreased or slower muscle movement
- racing heartbeat
- swelling that may involve the face, trunk and limbs
- abnormal blood test results suggesting problems with the liver
- mental impairment
- falls
- increase in blood glucose levels (most often observed in patients with diabetes)
- difficulty swallowing.

Rare (affects up to 1 in 1,000 people):

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

Since this medicine was first introduced to the market the following side effects have been reported (frequency unknown):

- decreased platelets (blood clotting cells)
- hallucinations
- problems with abnormal movements such as writhing, jerking movements and stiffness
- ringing in the ears
- a combination of side effects that could include swollen lymph nodes (isolated small raised lumps under the skin), fever, rash, and inflammation of liver
- yellowing of the skin and eyes (jaundice), inflammation of the liver
- acute kidney failure, incontinence
- increased breast tissue, male breast enlargement
- adverse events after suddenly stopping Gabapentin Oral Solution (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.

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 via the Yellow Card Scheme. Website: 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 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. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Once the bottle is opened, **use within 1 month**.
- Do not throw away any medicines via wastewater. 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 Oral Solution contains

- The active substance is gabapentin. Each ml contains 50mg gabapentin.
- The other ingredients are:
 - Sodium methyl parahydroxybenzoate (E219)
 - Sodium propyl parahydroxybenzoate (E217)
 - Propylene glycol
 - Sodium carmellose (Blanose 7MF)
 - Acesulfame potassium
 - Orange flavour (contains ethanol (alcohol))
 - Hydrochloric acid solution 17%
 - Purified water.

What Gabapentin Oral Solution looks like and contents of the pack

- Gabapentin Oral Solution is a clear colourless liquid with an orange flavour supplied in a 150ml amber glass bottle with a child resistant cap.
- Each carton includes a CE marked, 10ml graduated oral dosing syringe and a "press-in" syringe/bottle adaptor.

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