

Package leaflet: Information for the user

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

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 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 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. 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.

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

- 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).
- **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.
- 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, sedation, decrease in breathing, or death.

- **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 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

Gabapentin Oral Solution can be used during the first trimester of pregnancy if needed after careful consultation with your doctor.

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).

- **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 propylene glycol, acesulfame potassium, benzyl alcohol, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate and sodium:

- This medicine contains 42.85 mg **propylene glycol** per 1 ml. If you are pregnant or 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.
- This medicine contains 1.55 mg **potassium** per 1 ml. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
- This medicine contains 0.08 mg **benzyl alcohol** in each 1 ml. Benzyl alcohol may cause **allergic reactions**. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding, or 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”).
- **Parahydroxybenzoates** may cause **allergic reactions** (possibly delayed).
- This medicine contains 0.74 mg **sodium** (main component of cooking/table salt) in each 1 ml. This is equivalent to 0.04% of the recommended maximum daily dietary intake of sodium for an adult.

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. Do not take more medicine than prescribed.

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.

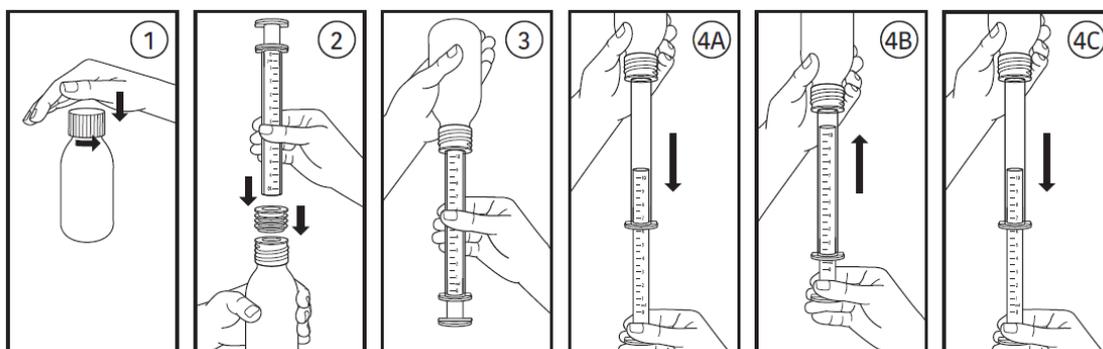
If you are an elderly patient (over 65 years of age), you should take the normal dose of Gabapentin Oral Solution unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

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.

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 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. Repeat steps 3 to 7 if necessary to take the full dose prescribed by your doctor.
9. Wash the syringe with water and let it dry before you use it again.
10. 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 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 is stopped it should be done gradually over a **minimum of 1 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 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.

- anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment).

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):

- agitation (a state of chronic restlessness and unintentional and purposeless motions)
- 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 not known (cannot be estimated from available data):

- 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, 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 (creatinine phosphokinase increased)
- problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation
- low blood sodium level
- 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 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 (E1520)
 - Sodium carmellose (Blanose 7MF), (E466)
 - Acesulfame potassium (E950)
 - Orange flavour (contains propylene glycol (E1520) and benzyl alcohol (E1519))
 - Hydrochloric acid solution 17% (E507)
 - 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.

Marketing Authorisation Holder

Colonis Pharma Ltd

25 Bedford Square
Bloomsbury
London
WC1B 3HH
United Kingdom

Manufacturers

Rafarm S.A.
Thesi Pousi-Xatzi Agiou Louka,
Paiania Attiki, TK19002, TΘ 37,
Greece

This leaflet was last revised in April 2024.