

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gabapentin Noumed 100mg Capsules

Gabapentin Noumed 300mg Capsules

Gabapentin Noumed 400mg Capsules

This medicine contains Gabapentin, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly. If this medicine is being used for the treatment of epilepsy you must continue to take this medicine as instructed by your doctor.

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

1. WHAT GABAPENTIN NOUMED IS AND WHAT IT IS USED FOR

Gabapentin Noumed 100mg, 300mg or 400mg Capsules (called Gabapentin Noumed throughout this leaflet) has been prescribed to you for the treatment of epilepsy and peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

The active substance in Gabapentin Noumed Capsules is Gabapentin which belongs to a class of medicines called Gabapentinoids.

This medicine has been prescribed by your doctor or pharmacist to you and should not be given to anyone else.

Gabapentin Noumed can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months. If this medicine is being used for the treatment of epilepsy you must continue to take it as prescribed by your doctor.

Gabapentin Noumed 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 treating you or your child 6 years of age and older will prescribe Gabapentin Noumed 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 Noumed in addition to your current treatment unless told otherwise. Gabapentin Noumed can also be used on its own to treat adults and children over 12 years of age.
- 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.

You must talk to a doctor if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GABAPENTIN NOUMED
Do not take Gabapentin Noumed:

- If you are allergic (hypersensitive) to gabapentin or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions:

Talk to your doctor or pharmacist before taking Gabapentin Noumed:

- 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.
- Before taking this medicine, tell your doctor if you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Gabapentin Noumed to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include:

- trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Gabapentin Noumed should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of Gabapentin Noumed, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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

A small number of people being treated with antiepileptics such as Gabapentin Noumed 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 Gabapentin Noumed (a need to keep taking the medicine).

They may have withdrawal effects when they stop using Gabapentin Noumed (see section 3, "How to take Gabapentin Noumed" and "If you stop taking Gabapentin Noumed"). If you have concerns that you may become dependent on Gabapentin Noumed, it is important that you consult your doctor.

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking Gabapentin Noumed, it could be a sign that you have become dependent.

- You feel you need to keep taking the medicine for longer than advised by your doctor.
- 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 signs, 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. A small number of people being treated with anti-epileptics such as Gabapentin Noumed have had thoughts of harming or killing

themselves. If at any time you have these thoughts, immediately contact your doctor.

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 Noumed. Stop using Gabapentin Noumed 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 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 Noumed

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. 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 Gabapentin Noumed. In addition, combination of Gabapentin Noumed with opioids may cause symptoms like sleepiness, sedation, decrease in breathing or death.

Antacids for indigestion

If Gabapentin Noumed and antacids containing aluminium and magnesium are taken at the same time, absorption of Gabapentin Noumed from the stomach may be reduced. It is therefore recommended that Gabapentin Noumed is taken at the earliest two hours after taking an antacid.

Gabapentin Noumed:

- Is not expected to interact with other antiepileptic drugs 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.

Gabapentin Noumed with food and drink:

Gabapentin Noumed 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
- If you are planning to become pregnant you should discuss your treatment with your doctor as early as possible before you become pregnant
- You should not stop your treatment without discussing this with your doctor.
- If you are breastfeeding or planning to breastfeed, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy:

Gabapentin Noumed can be used during the first trimester of pregnancy if needed.

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.

There have been very few studies specifically looking at the use of Gabapentin Noumed in pregnant women. In a study reviewing data from women in Nordic countries who took Gabapentin Noumed 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 Noumed during pregnancy had an increased risk of low birth weight and preterm birth. More research is needed to better understand the safety of use of Gabapentin Noumed during pregnancy and whether it is associated with an increased risk of harm to the unborn child.

Some medicines used to treat epilepsy have reported an increased risk of harm to the developing baby, particularly when more than one seizure medication is taken at the same time. This means that where possible, your doctor should consider using one epilepsy medicine to control your epilepsy.

If used during pregnancy, Gabapentin Noumed may lead to withdrawal symptoms in newborn infants. This risk might be increased when Gabapentin Noumed 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 Gabapentin Noumed. 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 Noumed. Ask your doctor or pharmacist for advice before taking any medicine.

Fertility:

There is no effect on fertility in animal studies.

Driving and using machines:

Gabapentin Noumed may cause 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.

3. HOW TO TAKE GABAPENTIN NOUMED

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.

Your doctor should have discussed with you how long the course of Gabapentin Noumed will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your Doctor will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Epilepsy, the recommended dose is
Adults and adolescents:

Take the number of capsules as instructed. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300mg and 900mg each day.

Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 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 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 25-35 mg per kg of body weight per day.

It is usually given in 3 separate doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.

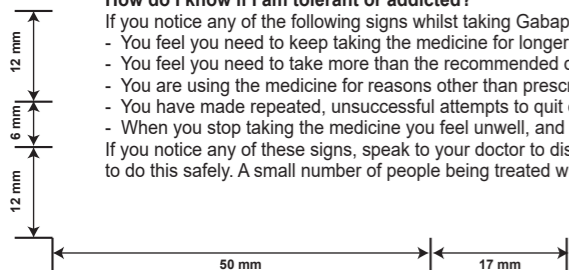
Gabapentin Noumed is not recommended for use in children below 6 years of age.

Peripheral Neuropathic Pain, the recommended dose is

Adults: Take the number of capsules as instructed by your doctor. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor up to a maximum of 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 Gabapentin Noumed 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 Noumed until your doctor tells you to stop. If you have the impression that the effect of Gabapentin Noumed is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Route of administration:

Gabapentin Noumed is for oral use. Always swallow the capsules whole with plenty of water. Continue taking Gabapentin Noumed until your doctor tells you to stop.

If you take more Gabapentin Noumed 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 Noumed than your doctor prescribed.

Take along any capsules that you have not taken, together with the container and the label so that the hospital can easily tell what medicine you have taken.

If you forget to take Gabapentin Noumed

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 Noumed

Do not stop taking Gabapentin Noumed unless your doctor tells you to. If you want to stop taking Gabapentin Noumed, discuss this with your doctor first. They will tell you how to do this. If your treatment is to be stopped it should be done by reducing the dose gradually over a period of weeks to months so that any unpleasant withdrawal effects are kept to a minimum. If you stop taking Gabapentin Noumed suddenly or before your doctor tells you, there is an increased risk of seizures. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms. After stopping a short or long-term treatment with Gabapentin Noumed, 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, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, thoughts of harming or killing yourself, dizziness, and feeling generally unwell. These effects usually occur within 48 hours after stopping Gabapentin Noumed. 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 Noumed 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 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
- Gabapentin Noumed 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 Gabapentin Noumed. Call your doctor right away if you have any of the following symptoms:
 - skin rash
 - fever
 - swelling of your lip and tongue
 - unusual bruising or bleeding
 - unexpected muscle pain
 - hives
 - swollen glands that do not go away
 - yellowing of your skin or of the whites of the eyes
 - severe fatigue or weakness
 - 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 Noumed.

- 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 tired, fever
- feeling drowsy, dizziness, lack of coordination

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
- Anger towards others, confusion, mood changes, depression, anxiety, nervousness, difficulty with thinking
- Anorexia, increased appetite
- 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
- Swelling that may involve the face, trunk and limbs
- Abnormal blood test results suggesting problems with the liver
- Mental impairment
- Fall
- Difficulty with thinking
- Increase in blood glucose levels (most often observed in patients with diabetes)
- Difficulty swallowing

Rare (may affect 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).

Frequency not known (cannot be estimated from available data):

- Suicidal thoughts
- Becoming dependent or addicted to Gabapentin Noumed ("see section "How do I know if I am tolerant or addicted?")
- Decreased platelets (blood clotting cells)
- bruising more easily than usual. This could be because of a blood problem (thrombocytopenia),
- seeing or hearing things which are not there (hallucinations),
- problems with abnormal movements such as writhing, jerking movements and stiffness,
- ringing in the ears (tinnitus),
- serious kidney disease (acute kidney failure), incontinence
- side effects following the sudden stopping of Gabapentin noumed (anxiety, difficulty in sleeping, feeling sick, pain, sweating), chest pain,
- blood glucose variations in patients with diabetes,
- breast enlargement in men or women,
- a group of side effects that could include swollen lymph nodes (isolated small raised lumps under skin), fever, rash, and inflammation of liver occurring together,
- Yellowing of the skin and eyes (jaundice), inflammation of the liver
- alopecia (hair loss).
- Breakdown of muscle fibers (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
- Anaphylaxis (serious, potentially life-threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)

After stopping a short or long-term treatment with Gabapentin Noumed, you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking Gabapentin Noumed").

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 relevant national reporting system detailed below: UK 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 affects you can help provide more information on the safety of this medicine.

5. HOW TO STORE GABAPENTIN NOUMED CAPSULES

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

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 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 Noumed Capsules contains**

The active substance is Gabapentin. Each capsule contains either 100mg, 300mg or 400mg of gabapentin.

The other ingredients are:

- **Capsules Fill** (100mg, 300mg, 400mg) - Maize Starch, Pregelatinised Maize Starch (1500), Talc.
- **Capsule shell:**
 - (100mg Capsule Shell) -Titanium Dioxide (E171), Gelatin.
 - (300mg Capsule Shell) - Yellow Iron Oxide (E172), Titanium Dioxide (E171), Gelatin
 - (400mg Capsule Shell) - Yellow Iron Oxide (E172), Red Iron Oxide (E172), Titanium Dioxide (E171), Gelatin

What Gabapentin Noumed Capsules looks like and contents of the pack

Gabapentin Noumed 100mg Capsules are white/white hard gelatin capsules.
 Gabapentin Noumed 300mg Capsules are yellow/yellow hard gelatin capsules.
 Gabapentin Noumed 400mg Capsules are orange/orange hard gelatin capsules.

Pack Size: 100

This leaflet was last revised in November 2025.

Marketing Authorisation Holder and Manufacturer:

NOUMED LIFE SCIENCES LIMITED

Noumed House, Shoppenhangers Road,
 Maidenhead, Berkshire, SL6 2RB, United Kingdom.



To listen to or request a copy of this leaflet in Braille, large print or audio, please call 020 33 99 8960 (UK only).

Please be ready to give the following information

Product Name	Reference Number
Gabapentin Noumed 100mg Capsules	PL 44041/0019
Gabapentin Noumed 300mg Capsules	PL 44041/0020
Gabapentin Noumed 400mg Capsules	PL 44041/0021

Signature of Author:				Font size & Type	Arial bold - 11	
Signature of RA:					Arial regular - 7.25	
				Title: Art Work Approval Form		
Product	Gabapentin Noumed PIL			Specification:	n/a	
Customer	NOUMED LIFE SCIENCES LIMITED, UK					
Reason for Issue	Content edit			Colours:	Black	
				Dimensions:	340 x 290	
PL No.	n/a	Pharmacode No.	n/a	No. of Folds (only for PIL)	n/a	n/a
Item Code	LGAB02/05	Layout No.:	n/a			

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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.
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1. WHAT GABAPENTIN NOUMED IS AND WHAT IT IS USED FOR

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The active substance in Gabapentin Noumed Capsules is Gabapentin which belongs to a class of medicines called Gabapentinoids.

This medicine has been prescribed by your doctor or pharmacist to you and should not be given to anyone else.

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Gabapentin Noumed 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 treating you or your child 6 years of age and older will prescribe Gabapentin Noumed 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 Noumed in addition to your current treatment unless told otherwise. Gabapentin Noumed can also be used on its own to treat adults and children over 12 years of age.
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You must talk to a doctor if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GABAPENTIN NOUMED
Do not take Gabapentin Noumed:

- If you are allergic (hypersensitive) to gabapentin or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions:

Talk to your doctor or pharmacist before taking Gabapentin Noumed:

- 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.
- Before taking this medicine, tell your doctor if you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Gabapentin Noumed to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include:

- trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Gabapentin Noumed should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of Gabapentin Noumed, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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

A small number of people being treated with antiepileptics such as Gabapentin Noumed 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 Gabapentin Noumed (a need to keep taking the medicine).

They may have withdrawal effects when they stop using Gabapentin Noumed (see section 3, "How to take Gabapentin Noumed" and "If you stop taking Gabapentin Noumed"). If you have concerns that you may become dependent on Gabapentin Noumed, it is important that you consult your doctor.

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking Gabapentin Noumed, it could be a sign that you have become dependent.

- You feel you need to keep taking the medicine for longer than advised by your doctor

- 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 signs, 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. A small number of people being treated with anti-epileptics such as Gabapentin Noumed have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

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 Noumed. Stop using Gabapentin Noumed 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 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 Noumed

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. 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 Gabapentin Noumed. In addition, combination of Gabapentin Noumed with opioids may cause symptoms like sleepiness, sedation, decrease in breathing or death.

Antacids for indigestion

If Gabapentin Noumed and antacids containing aluminium and magnesium are taken at the same time, absorption of Gabapentin Noumed from the stomach may be reduced. It is therefore recommended that Gabapentin Noumed is taken at the earliest two hours after taking an antacid.

Gabapentin Noumed:

- Is not expected to interact with other antiepileptic drugs 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.

Gabapentin Noumed with food and drink:

Gabapentin Noumed 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
- If you are planning to become pregnant you should discuss your treatment with your doctor as early as possible before you become pregnant
- You should not stop your treatment without discussing this with your doctor.
- If you are breastfeeding or planning to breastfeed, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy:

Gabapentin Noumed can be used during the first trimester of pregnancy if needed.

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.

There have been very few studies specifically looking at the use of gabapentin in pregnant women. In a study reviewing data from women in Nordic countries who took Gabapentin Noumed 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 Noumed during pregnancy had an increased risk of low birth weight and preterm birth. More research is needed to better understand the safety of use of Gabapentin Noumed during pregnancy and whether it is associated with an increased risk of harm to the unborn child. Some medicines used to treat epilepsy have reported an increased risk of harm to the developing baby, particularly when more than one seizure medication is taken at the same time. This means that where possible, your doctor should consider using one epilepsy medicine to control your epilepsy.

If used during pregnancy, Gabapentin Noumed may lead to withdrawal symptoms in newborn infants. This risk might be increased when Gabapentin Noumed 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 Gabapentin Noumed. 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 Noumed. Ask your doctor or pharmacist for advice before taking any medicine.

Fertility:

There is no effect on fertility in animal studies.

Driving and using machines:

Gabapentin Noumed may cause 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.

3. HOW TO TAKE GABAPENTIN NOUMED

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.

Your doctor should have discussed with you how long the course of Gabapentin Noumed will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your Doctor will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Epilepsy, the recommended dose is
Adults and adolescents:

Take the number of capsules as instructed. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300mg and 900mg each day. Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 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 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 25-35 mg per kg of body weight per day. It is usually given in 3 separate doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.
Gabapentin Noumed is not recommended for use in children below 6 years of age.

Peripheral Neuropathic Pain, the recommended dose is

Adults: Take the number of capsules as instructed by your doctor. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor up to a maximum of 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 Gabapentin Noumed 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 Noumed until your doctor tells you to stop.

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

Route of administration:

Gabapentin Noumed is for oral use. Always swallow the capsules whole with plenty of water.

Continue taking Gabapentin Noumed until your doctor tells you to stop.

If you take more Gabapentin Noumed 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 Noumed than your doctor prescribed.

Take along any capsules that you have not taken, together with the container and the label so that the hospital can easily tell what medicine you have taken.

If you forget to take Gabapentin Noumed

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 Noumed

Do not stop taking Gabapentin Noumed unless your doctor tells you to. If you want to stop taking Gabapentin Noumed, discuss this with your doctor first. They will tell you how to do this. If your treatment is to be stopped it should be done by reducing the dose gradually over a period of weeks to months so that any unpleasant withdrawal effects are kept to a minimum. If you stop taking Gabapentin Noumed suddenly or before your doctor tells you, there is an increased risk of seizures. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

After stopping a short or long term treatment with Gabapentin Noumed, 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, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, thoughts of harming or killing yourself, dizziness, and feeling generally unwell. These effects usually occur within 48 hours after stopping Gabapentin Noumed. 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 Noumed 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 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
- Gabapentin Noumed 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 Gabapentin Noumed. 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

These symptoms may be the first signs of a serious reaction.

A doctor should examine you to decide if you should continue taking Gabapentin Noumed.

- 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 (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
- Swelling that may involve the face, trunk and limbs
- Abnormal blood test results suggesting problems with the liver
- Mental impairment
- Fall
- Difficulty with thinking
- Increase in blood glucose levels (most often observed in patients with diabetes)
- Difficulty swallowing

Rare (may affect 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).

Frequency not known (cannot be estimated from available data):

- Suicidal thoughts
- Becoming dependent or addicted to Gabapentin Noumed ('see section "How do I know if I am tolerant or addicted?")
- Decreased platelets (blood clotting cells)
- bruising more easily than usual. This could be because of a blood problem (thrombocytopenia),
- seeing or hearing things which are not there (hallucinations),
- problems with abnormal movements such as writhing, jerking movements and stiffness,
- ringing in the ears (tinnitus),
- serious kidney disease (acute kidney failure), incontinence
- side effects following the sudden stopping of Gabapentin noumed (anxiety, difficulty in sleeping, feeling sick, pain, sweating), chest pain,
- blood glucose variations in patients with diabetes,
- breast enlargement in men or women,
- a group of side effects that could include swollen lymph nodes (isolated small raised lumps under skin), fever, rash, and inflammation of liver occurring together,
- Yellowing of the skin and eyes (jaundice), inflammation of the liver
- alopecia (hair loss).
- Breakdown of muscle fibers (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)

After stopping a short or long-term treatment with Gabapentin Noumed, you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking Gabapentin Noumed").

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 relevant national reporting system detailed below: UK 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 NOUMED CAPSULES

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

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 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 Noumed Capsules contains

The active substance is Gabapentin. Each capsule contains either 100mg, 300mg or 400mg of gabapentin.

The other ingredients are:

- **Capsules Fill** (100mg, 300mg, 400mg) - Maize Starch, Pregelatinised Maize Starch (1500), Talc.
- **Capsule shell:**
 - (100mg Capsule Shell) - Titanium Dioxide (E171), Gelatin.
 - (300mg Capsule Shell) - Yellow Iron Oxide (E172), Titanium Dioxide (E171), Gelatin
 - (400mg Capsule Shell) - Yellow Iron Oxide (E172), Red Iron Oxide (E172), Titanium Dioxide (E171), Gelatin

What Gabapentin Noumed Capsules looks like and contents of the pack

Gabapentin Noumed 100mg Capsules are white/white hard gelatin capsules. Gabapentin Noumed 300mg Capsules are yellow/yellow hard gelatin capsules. Gabapentin Noumed 400mg Capsules are orange/orange hard gelatin capsules. Pack Size: 100

This leaflet was last revised in November 2025.

Marketing Authorisation Holder and Manufacturer:

NOUMED LIFE SCIENCES LIMITED
Noumed House, Shoppenhangers Road,
Maidenhead, Berkshire, SL6 2RB, United Kingdom.



To listen to or request a copy of this leaflet in Braille, large print or audio, please call 020 33 99 8960 (UK only). Please be ready to give the following information

Product Name	Reference Number
Gabapentin Noumed 100mg Capsules	PL 44041/0019
Gabapentin Noumed 300mg Capsules	PL 44041/0020
Gabapentin Noumed 400mg Capsules	PL 44041/0021

Signature of Author:					
Signature of RA:				Font size & Type	Arial bold - 11
Approval:					Arial regular - 7
				Title: Art Work Approval Form	
Product	Gabapentin Noumed PIL			Specification:	n/a
Customer	NOUMED LIFE SCIENCES LIMITED, UK			Colours:	Black
Reason for Issue	content update			Dimensions:	200 x 340
PL No.	n/a	Pharmacode No.	n/a	No. of Folds (only for PIL)	n/a
Item Code	LGAB03/05	Layout No.:	n/a		n/a