

**Package leaflet: Information for the user**  
**Gabapentin Thame 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.

The name of your medicine is Gabapentin Thame 50mg/ml Oral Solution but it will be referred to as Gabapentin throughout this leaflet.

**What is in this leaflet:**

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

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

Gabapentin contains the active substance gabapentin which belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long-lasting pain caused by damage to the nerves).  
You must talk to a doctor if you do not feel better or if you feel worse.

**Gabapentin is used to treat**

- ▶ Various forms of epilepsy (seizures that are initially limited to certain parts of the brain, whether the seizure spreads to other parts of the brain or not). Your doctor will prescribe Gabapentin for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Gabapentin in addition to your current treatment unless told otherwise. Gabapentin can also be used on its own to treat adults and children over 12 years of age.
- ▶ Peripheral neuropathic pain (long-lasting pain caused by damage to the nerves). A variety of different diseases can cause peripheral neuropathic pain (primarily occurring in the legs and/or arms), such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles etc.

**2. What you need to know before you take Gabapentin**

**Do not take Gabapentin:**

- ▶ If you are allergic (hypersensitive) 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:
- ▶ 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 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.

**Dependence**

Some people may become dependent on Gabapentin (a need to keep taking the medicine). They may have

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

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

- ▶ You feel you need to take the medicine for longer than advised by your prescriber
- ▶ You feel you need to take more than the recommended dose
- ▶ You are using the medicine for reasons other than prescribed
- ▶ You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- ▶ When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to do this safely.

Cases of abuse and dependence have been reported for gabapentin 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 anti-epileptics such as Gabapentin have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

**Important information about potentially serious reactions**

Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with gabapentin. **Stop using gabapentin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.**

**Read the description of 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**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor (or pharmacist) if you are taking or have been recently taking any medicines for convulsions, sleeping disorders, depression, anxiety, or any other neurological or psychiatric problems.

**Medicines containing opioids such as morphine**

If you are taking any medicines containing opioids (such as morphine), please tell your doctor or pharmacist as opioids may increase the effect of Gabapentin. In addition, combination of Gabapentin with opioids may cause symptoms like sleepiness and/or decrease in breathing.

**Antacids for indigestion**

If you are taking any medicines containing antacids (such as morphine), please tell your doctor or pharmacist as antacids may increase the effect of Gabapentin. In addition, combination of Gabapentin with antacids may cause sleepiness, sedation, decrease in breathing, or death.

**Gabapentin**

- ▶ Is not expected to interact with other antiepileptic drug 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 with food**

Gabapentin can be taken with or without food.

**Pregnancy, breast-feeding and fertility**

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

**Pregnancy**

Gabapentin should not be taken during pregnancy, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential.

There have been no studies specifically looking at the use of gabapentin in pregnant women, but other medications used to treat seizures have reported an increased risk of harm to the developing baby, particularly when more than one seizure medication is taken at the same time. Therefore, whenever possible, you should try to take only one seizure medication during pregnancy and only under the advice of your doctor.

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking this medicine. Do not suddenly discontinue taking this medicine as this may lead to breakthrough seizure, which could have serious consequences for you and your baby.

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).

**Breast-feeding**

Gabapentin is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using Gabapentin.

**Fertility**

There is no effect on fertility in animal studies.

**Driving and using machines**

Gabapentin may produce dizziness, drowsiness and tiredness. You should not drive, operate complex machinery or take part in other potentially hazardous activities until you know whether this medication affects your ability to perform these activities.

**Gabapentin contains:**

- **Methyl parahydroxybenzoate (E218) and Ethyl parahydroxybenzoate (E214)**, which may cause allergic reactions (possibly delayed).
- **Propylene glycol (E1520)**: Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce serious adverse effects in neonates.
- This medicine contains less than 1 mmol **sodium** (23 mg) per dose (300mg gabapentin), that is to say essentially 'sodium-free'.

**3. How to take Gabapentin**

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.

**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 years and above:**

The dose to be given to your child will be decided by your doctor as it is calculated against your child's weight. The treatment is started with a low initial dose which is gradually increased over a period of approximately 3 days. The usual dose to control epilepsy is 0.5ml-0.7ml (25-35mg) per kg of body weight per day. It is usually given in 3 separate doses each day, usually once in the morning, once in the afternoon and once in the evening.

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

**Peripheral neuropathic pain, the recommended dose is**

**Adults:**

Your doctor will usually build up your dose gradually. The starting dose will generally be between 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 unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

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

**Route and Method of administration:**

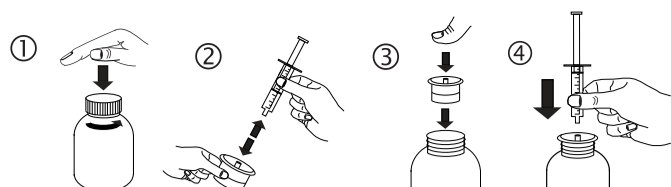
This medicinal product must be taken orally.  
Use the measuring syringe provided in the pack to deliver the required dose.  
For higher dose, you may require to repeat the below steps. The examples for number of withdrawals required for higher doses are provided below:

Dose in mg	Dose in ml	Volume to be withdrawn with the syringe
300mg	6ml	6ml in one withdrawal
900mg	18ml	1 full syringe plus 8ml in second withdrawal
1200mg three times a day (3600mg as maximum daily dose)	24ml three times a day (72ml as maximum daily dose)	2 full syringe plus 4ml in third withdrawal (To be taken three times a day)

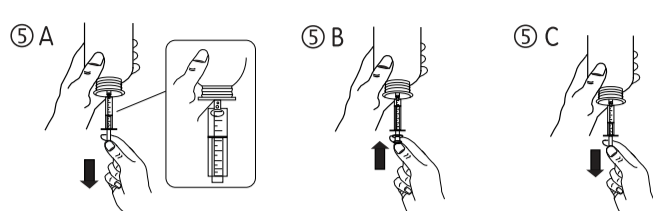
**Instructions for the use of syringe:**

- a) Open the bottle: press the cap and turn it anticlockwise (figure 1).
- b) Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).

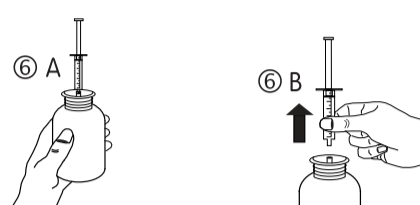
**TURN OVER**



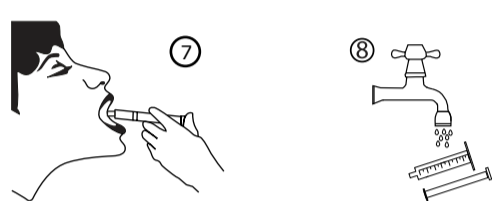
c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



e) Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Leave the syringe adaptor in place after first use. Close the container with the plastic screw cap. Wash the syringe with water (figure 8).



#### If you take more Gabapentin than you should

Higher than recommended doses may result in an increase in side effects including loss of consciousness, dizziness, double vision, slurred speech, drowsiness and diarrhoea. Call your doctor or go to the nearest hospital emergency unit immediately if you take more Gabapentin than your doctor prescribed. Take along any leftover medicine with you, as well as the container and the label so that the hospital can easily tell what medicine you have taken.

#### If you forget to take Gabapentin

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

Do not suddenly stop taking Gabapentin. If you want to stop taking Gabapentin, 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, 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. If you experience withdrawal effects, you should contact your doctor.

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

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### Stop using Gabapentin and seek medical attention immediately if you notice any of the following symptoms:

- ▶ **reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).**
- ▶ **Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).**

#### Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious:

- ▶ **Severe skin reactions that require immediate attention, swelling of the lips and face, skin rash and redness, and/or hair loss (these may be symptoms of a serious allergic reaction.)**
- ▶ **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 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 a rash when you get this type of reaction. It may cause you to be hospitalized or to stop Gabapentin. 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.**

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

Other side effects include:

#### Very common: (may affect more than 1 in 10 people)

- ▶ Viral infection
- ▶ Feeling drowsy, dizziness, lack of coordination
- ▶ Feeling tired, fever.

#### Common: (may affect up to 1 in 10 people)

- ▶ Pneumonia, respiratory infections, urinary tract infection, inflammation of the ear or other infections
- ▶ Low white blood cell counts
- ▶ Anorexia, increased appetite
- ▶ Anger towards others, confusion, mood changes, depression, anxiety, nervousness, difficulty with thinking
- ▶ Convulsions, jerky movements, difficulty with speaking, loss of memory, tremor, difficulty sleeping, headache, sensitive skin, decreased sensation (numbness), difficulty with coordination, unusual eye movement, increased, decreased or absent reflexes
- ▶ Blurred vision, double vision

- ▶ Vertigo
  - ▶ High blood pressure, flushing or dilation of blood vessels
  - ▶ Difficulty breathing, bronchitis, sore throat, cough, dry nose
  - ▶ Vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhoea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
  - ▶ Facial swelling, bruises, rash, itch, acne
  - ▶ Joint pain, muscle pain, back pain, twitching
  - ▶ Difficulties with erection (impotence)
  - ▶ Swelling in the legs and arms, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
  - ▶ Decrease in white blood cells, increase in weight
  - ▶ Accidental injury, fracture, abrasion.
- Additionally in clinical studies in children, aggressive behaviour and jerky movements were reported commonly.

#### Uncommon: (may affect up to 1 in 100 people)

- ▶ Agitation (a state of chronic restlessness and unintentional and purposeless motions)
- ▶ Allergic reaction such as hives
- ▶ Decreased movement
- ▶ Racing heartbeat
- ▶ Difficulty swallowing
- ▶ Swelling that may involve the face, trunk and limbs
- ▶ Abnormal blood test results suggesting problems with the liver
- ▶ Mental impairment
- ▶ Fall
- ▶ Increase in blood glucose levels (most often observed in patients with diabetes)

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

- ▶ Decrease in blood glucose levels (most often observed in patients with diabetes)
- ▶ Loss of consciousness
- ▶ Trouble breathing, shallow breaths (respiratory depression).

#### Not known: frequency cannot be estimated from the available data

- ▶ Becoming dependent on Gabapentin ('drug dependence')

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

#### After marketing of Gabapentin the following side effects have been reported:

- ▶ Decreased platelets (blood clotting cells)
- ▶ Suicidal thoughts, Hallucinations
- ▶ Problems with abnormal movements such as writhing, jerking movements and stiffness
- ▶ Ringing in the ears
- ▶ Yellowing of the skin and eyes (jaundice), inflammation of the liver
- ▶ Acute kidney failure, incontinence
- ▶ Increased breast tissue, breast enlargement
- ▶ Adverse events following the abrupt discontinuation of gabapentin (anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
- ▶ Breakdown of muscle 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).

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

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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](http://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

- ▶ 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 or bottle after EXP. The expiry date refers to the last day of that month.
- ▶ Do not store above 25°C. Do not refrigerate or freeze.
- ▶ Discard 30 days after first opening.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What Gabapentin contains

The active substance is gabapentin.

Each ml of oral solution contains 50mg gabapentin.

The other ingredients are acesulfame potassium (E950), saccharin sodium (E954), propylene glycol (E1520), methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), carmellose sodium (E466) and purified water.

#### What Gabapentin looks like and contents of the pack

Gabapentin is a clear, colourless oral solution supplied in an amber glass bottle fitted with a child-resistant plastic cap and a 10ml oral syringe with 0.5ml graduation and a bottle adaptor for syringe.

Gabapentin is supplied in bottles containing 150ml of solution.

#### POM

#### Marketing Authorisation Holder:

Thame Laboratories  
Unit 4, Bradfield Road,  
Ruislip, Middlesex,  
HA4 0NU, UK.

#### Manufacturer:

Delpharm Bladel B.V.  
Industrieweg 1,  
5531 AD Bladel,  
Netherlands

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**  
**MT and UK (NI):** Gabapentin Thame 50mg/ml Oral Solution

**If this leaflet is hard to see or read, please call +44(0) 208 515 3700 for help.**

This leaflet was last revised in 07/2023.