

30 mm



**Package leaflet: Information for the patient**  
**Gabapentin Tillomed 100mg hard capsules**  
**Gabapentin Tillomed 300mg hard capsules**  
**Gabapentin Tillomed 400mg hard capsules**  
 Gabapentin

**Read all of this leaflet carefully before you start using 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

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

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

Gabapentin Tillomed belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

The active substance in Gabapentin Tillomed is gabapentin.

**Gabapentin Tillomed 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 Tillomed for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Gabapentin Tillomed in addition to your current treatment unless told otherwise. Gabapentin Tillomed 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 or pins and needles.

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

**Do not take Gabapentin Tillomed**

- 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 Tillomed

- if you suffer from kidney problems, your doctor may prescribe a different dosing schedule
- if you are on haemodialysis (to remove waste products because of kidney failure), tell your doctor if you develop muscle pain and/or weakness
- if you develop signs such as persistent stomach pain, feeling sick and being sick, contact your doctor immediately, as these may be symptoms of acute pancreatitis (an inflamed pancreas)
- if you have nervous system disorders, respiratory disorders, or you are more than 65 years old, your doctor may prescribe you a different dosing regimen.

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

A small number of people being treated with antiepileptics 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**

A small number of people taking Gabapentin get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. You need to know the symptoms to look out for while you are taking Gabapentin.

**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 increase). If you experience any of these signs or symptoms, please contact your doctor immediately.

**Other medicines and Gabapentin Tillomed**

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 Tillomed. In addition, combination of Gabapentin Tillomed with opioids may cause symptoms like sleepiness and/or a decrease in breathing.

Antacids for indigestion

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

Gabapentin Tillomed

- 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 Tillomed with food**

Gabapentin Tillomed may be taken with or without food.

**Pregnancy and breast-feeding**

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 Tillomed should not be taken during pregnancy, unless you are told otherwise by your doctor. Effective contraception must be used by women of childbearing potential.

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

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Gabapentin Tillomed. 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, the active substance of Gabapentin Tillomed, is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breastfeed while using Gabapentin Tillomed.

Fertility

There is no effect on fertility in animal studies.

**Driving and using machines:**

Gabapentin Tillomed 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.

**Gabapentin Tillomed contains Mannitol**

Gabapentin Tillomed hard capsules contain mannitol which may have a mild laxative effect.

Gabapentin Tillomed hard capsules contain less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

**3 How to take Gabapentin Tillomed**

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 what dose is appropriate for you.

**Epilepsy**

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 three 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 then gradually increased over a period of approximately three days. The usual dose to control epilepsy is 25-35mg per kg of body weight per day. It is usually given in three separate doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.

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

**Peripheral Neuropathic Pain**

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 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 three 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 Tillomed 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 Tillomed is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

**Method of administration**

Gabapentin Tillomed is for oral use. Always swallow the capsules or tablets with plenty of water.

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

**If you take more Gabapentin Tillomed than you should**

Higher doses than recommended 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 Tillomed 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.

Width 170 mm

FRONT

Length 540 mm

30 mm

**If you forget to take Gabapentin Tillomed**

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 Tillomed**

Do not stop taking Gabapentin Tillomed unless your doctor tells you to. If your treatment is stopped, it should be done gradually over a minimum of one week. If you stop taking Gabapentin Tillomed suddenly, or before your doctor tells you, there is an increased risk of seizures.

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

**4 Possible side effects**

Like all medicines, 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 Tillomed 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 hospitalised or to stop taking Gabapentin Tillomed. Contact your doctor immediately 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 Tillomed.**

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
- 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)
- 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)

**After marketing Gabapentin Tillomed the following side effects have been reported:**

- Decreased platelets (blood clotting cells)
- Hallucinations
- Problems with abnormal movements such as writhing, jerking movements and stiffness
- Ringing in the ears
- A group of side effects that could include swollen lymph nodes (isolated small raised lumps under the skin), fever, rash, and inflammation of liver occurring together
- 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 fibres (rhabdomyolysis)
- Change in blood test results (creatinine phosphokinase increase)
- 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)

**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 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 Tillomed**

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 as 'Exp'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6 Contents of the pack and other information****What Gabapentin Tillomed contains**

The active substance is gabapentin. Each Gabapentin Tillomed 100mg hard capsule contains 100mg gabapentin.

Each Gabapentin Tillomed 300mg hard capsule contains 300mg gabapentin.

Each Gabapentin Tillomed 400mg hard capsule contains 400mg gabapentin.

The other ingredients are maize starch, mannitol and talc. The capsule shell contains gelatin, purified water, titanium dioxide (E171) and sodium lauryl sulfate. The printing ink contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution and FD & C Blue # 2 Aluminium Lake (E132).

**What Gabapentin Tillomed looks like and contents of the pack**

The 100mg capsules are white/white opaque size '3' hard gelatin capsules imprinted in blue ink with '100' on the cap and 'IG' on the body, containing white to off white powder.

The 300mg capsules are yellow/yellow opaque size '1' hard gelatin capsules imprinted in blue ink with '300' on the cap and 'IG' on the body, containing white to off white powder.

The 400mg capsules are orange/orange opaque size '0' hard gelatin capsules imprinted in blue ink with '400' on the cap and 'IG' on the body, containing white to off white powder.

Gabapentin Tillomed 100mg hard capsules are available in blister packs of 20, 50, 90, 100 and 200 capsules.

Gabapentin Tillomed 300mg hard capsules are available in blister packs of 30, 50, 90, 100 and 200 capsules.

Gabapentin Tillomed 400mg hard capsules are available in blister packs of 30, 50, 90, 100 and 200 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer****Marketing Authorisation Holder**

Tillomed Laboratories Ltd  
220 Butterfield Great Marlings,  
Luton LU2 8DL  
United Kingdom

**Manufacturer**

Tillomed Laboratories Ltd  
220 Butterfield, Great Marlings,  
Luton, LU2 8DL  
United Kingdom

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

United Kingdom	Gabapentin Tillomed 100mg hard capsules Gabapentin Tillomed 300mg hard capsules Gabapentin Tillomed 400mg hard capsules
Germany	Gabapentin Tillomed 100mg Hartkapseln Gabapentin Tillomed 300mg Hartkapseln Gabapentin Tillomed 400mg Hartkapseln
Spain	Gabapentin Tillomed 100mg cápsulas duras EFG Gabapentin Tillomed 300mg cápsulas duras EFG Gabapentin Tillomed 400mg cápsulas duras EFG
Italy	Gabanex

This leaflet was last revised in 05/2019.

Item code

Width 170 mm

BACK

Length 540 mm