PACKAGE LEAFLET
Package leaflet: Information for the user

Gabapentin Glenmark 600 mg film-coated tablets
Gabapentin Glenmark 800 mg film-coated tablets
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.
- 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.

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

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

This medicine has been prescribed for you for the treatment of epilepsy and/or peripheral neuropathic pain

It contains the Gabapentin which belongs to a class of medicines called Gabapentinoids.

This medicine has been prescribed to you and should not be given to anyone else.

Gabapentinoids 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 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 Glenmark Tablets is gabapentin.

Gabapentin Glenmark 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 Glenmark 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 Glenmark Film-coated Tablets in addition to the current treatment unless told otherwise. Gabapentin Glenmark Film-coated Tablets 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 Glenmark

Talk to your prescriber before taking this medicine 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 Glenmark 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.

Talk to your doctor or pharmacist before taking Gabapentin Glenmark

- If you have myasthenia gravis (a disease causing muscle weakness) because this medicine may make your symptoms worse

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.

Gabapentinoids 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 Gabapentinoids may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Do not take Gabapentin Glenmark:

- 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 Glenmark:

• 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 Glenmark

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.

Dependence

Some people may become dependent on Gabapentin Glenmark (a need to keep taking the medicine). They may have withdrawal effects when they stop using Gabapentin Glenmark (see section 3, “How to take Gabapentin Glenmark” and “If you stop taking Gabapentin Glenmark”). If you have concerns that you may become dependent on Gabapentin Glenmark, it is important that you consult your doctor.

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

- You feel you need to take the medicine for longer than advised by your prescriber

- You feel you need to take more than the recommended dose

-You are using the medicine for reasons other than prescribed

- You have made repeated, unsuccessful attempts to quit or control the use of the medicine

- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

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

Important information about potentially serious reactions

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 serious 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 Glenmark

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 sleepiness, sedation, decrease in breathing, or death.

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

Gabapentin Glenmark:
• 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 Glenmark with food
Gabapentin Glenmark can be taken with or without food.

Pregnancy, breast-feeding and fertility

- If you are pregnant or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the medicine you are taking might pose to your unborn baby.
- You should not stop your treatment without discussing this with your doctor.
- If you are planning to become pregnant you should discuss your treatment with your doctor. or pharmacist as early as possible before you become pregnant.
- If you are breastfeeding or planning to breastfeed, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Gabapentin Glenmark 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.

In a study reviewing data from women in Nordic countries who took gabapentin in the first 3 months of pregnancy, there was no increased risk of birth defects or problems with the development of brain function (neurodevelopment disorders). However, babies of women who took gabapentin during pregnancy had an increased risk of low birth weight and preterm birth.

If used during pregnancy, gabapentin may lead to withdrawal symptoms in newborn infants. This risk might be increased when gabapentin is taken together with opioid analgesics (drugs for treatment of severe pain).

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Gabapentin Glenmark. 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 Glenmark, is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using Gabapentin Glenmark.

Fertility

There is no effect on fertility in animal studies.

Driving and using machines

Gabapentin Glenmark film-coated tablets 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.

3. How to take Gabapentin Glenmark

Your prescriber should have discussed with you how long the course of tablets 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 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.

If you stop taking Gabapentin Glenmark

Do not suddenly stop taking this medicine or reduce your dose. If you want to stop taking this medicine or reduce your dose, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. 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.

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

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:
Take the number of tablets as instructed. 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.

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 per day. It is usually given in 3 separate doses, by taking the tablet(s) 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:
Take the number of tablets 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 this medicine 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 Glenmark Tablets is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Method of administration

Gabapentin Glenmark Tablets is for oral use. Always swallow the tablets with plenty of water.

The tablet can be divided into equal halves.

Continue taking this medicine until your doctor tells you to stop.

If you take more Gabapentin Glenmark 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 tablets 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 Glenmark

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 Glenmark

Do not suddenly stop taking Gabapentin Glenmark. If you want to stop taking Gabapentin Glenmark, 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 Glenmark, 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 Glenmark. 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 Glenmark 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:

• 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 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 and redness and/or hair loss
  - hives
  - fever
  - swollen glands that do not go away
  - swelling of your lip, face 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)
• Agitation (a state of chronic restlessness and unintentional and purposeless motions)

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)

Unknown frequency: dependence and addiction (see section "How do I know if I am tolerant or addicted?").

Drug Withdrawal

When you stop taking Gabapentin Glenmark, you may experience drug withdrawal symptoms, which include:
trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness.

After marketing 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)
- Becoming dependent on Gabapentin Glenmark ('drug dependence')

Not known (cannot be estimated from the available data)

- Worsening of myasthenia gravis (a disease causing muscle weakness)

How do I know if I am tolerant or addicted?

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

- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- 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, it is important you talk to your prescriber.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at

www.mhra.gov.co.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 Glenmark

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 blister / bottle and carton after "EXP". The expiry date refers to the last day of that month.

PVC/PVDC – Aluminum Blister Pack: Do not store above 25°C.

Aluminum – Aluminum Blister Pack and Bottle Pack: Do not store above 30°C.

Store in the original package in order to protect from moisture.

Only for bottles
Shelf life after first opening of the bottle: 120 days.

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 Glenmark contains

The active substance is gabapentin.
Each film-coated tablet contains 600 mg gabapentin.
Each film-coated tablet contains either 800 mg gabapentin.

The other ingredients are:

Tablet core: Poloxamer 407, copovidone, maize starch and magnesium stearate.
Film-coating: Ready to use coating material [Hypromellose (E464), Titanium Dioxide (E171), Macrogol 400 (E1521), Polysorbate 80 (E433)], Macrogol 8000 and Talc

What Gabapentin Glenmark looks like and contents of the pack

Film-coated tablet

White to off white, oval shaped, biconvex scored film coated tablets debossed with "G" and "31" on one side, approximately 17.40 ± 0.2 mm in length
The tablet can be divided into equal doses.

White to off white, oval shaped, biconvex scored film coated tablets debossed with "G" and "13" on one side, approximately 19.10 ± 0.2 mm in length
The tablet can be divided into equal doses.

Gabapentin Glenmark comes in blisters containing 1, 10, 30, 45, 50, 60, 84, 90, 100, 120, 180, 200 film-coated tablets and in bottles with 100, 500 and 1000 film-coated tablets.

Not all pack sizes may be marketed.

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