

GABAPENTIN TEVA 600 mg
FILM-COATED TABLETS
GABAPENTIN TEVA 800 mg
FILM-COATED TABLETS
Gabapentin

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

- What Gabapentin Teva is and what it is used for
- Before you take Gabapentin Teva
- How to take Gabapentin Teva
- Possible side effects
- How to store Gabapentin Teva
- Further information

1 WHAT GABAPENTIN TEVA IS AND WHAT IT IS USED FOR

Gabapentin Teva 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 ingredient in Gabapentin Teva is gabapentin.

Gabapentin Teva 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 Teva for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Gabapentin Teva in addition to your current treatment unless told otherwise. Gabapentin Teva 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 BEFORE YOU TAKE GABAPENTIN TEVA

Do NOT take Gabapentin Teva

- if you are allergic (hypersensitive) to gabapentin or any of the other ingredients of Gabapentin Teva.

Take special care with Gabapentin Teva

- if you suffer from kidney problems
- if you are on haemodialysis, 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.

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

A small number of people taking Gabapentin Teva 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 these symptoms to look out for while you are taking Gabapentin Teva.

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'

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking any medicines containing morphine, please tell your doctor or pharmacist as morphine may increase the effect of Gabapentin Teva.

Gabapentin Teva

- 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 that you are taking Gabapentin Teva.

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

Taking Gabapentin Teva with food and drink

Gabapentin Teva can be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Gabapentin Teva 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 foetus, 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.

Do not suddenly discontinue taking this medicine as this may lead to breakthrough seizure, which could have serious consequences for you and your baby.

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Gabapentin Teva.

Gabapentin, the active substance of Gabapentin Teva, is excreted in human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using Gabapentin Teva.

Driving and using machines

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

3 HOW TO TAKE GABAPENTIN TEVA

Always take Gabapentin Teva exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will determine what dose is appropriate for you.

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

If you are an elderly patient (over 65 years of age), you should take the normal dose of Gabapentin Teva 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 Teva until your doctor tells you to stop.

The usual dose for treating epilepsy:

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

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 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.

The usual dose for treating Peripheral Neuropathic Pain:

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.

Method and route of administration

Gabapentin Teva is for oral use. Always swallow the tablets whole with plenty of water.

If you take more Gabapentin Teva than you should

Higher than recommended doses may result in an increase in undesirable 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 Teva 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 Teva

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 Teva

Do not stop taking Gabapentin Teva unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week. If you stop taking Gabapentin Teva 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 product, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Gabapentin Teva 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 such as 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)
- Gabapentin Teva 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 Teva. 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 Teva.

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

Other side effects include:

Very common side-effects (which may affect more than 1 person in 10):

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

Common side-effects (which may affect more than 1 person in 100):

- Pneumonia, respiratory infection, urinary tract infection, other infections, inflammation of the ear
- Low white blood cell counts
- Anorexia, increased appetite
- Anger towards others, confusion, fluctuation in mood, depression, anxiety, nervousness, difficulty with thinking
- Convulsions, jerky movements, difficulty with speaking, loss of memory, tremor, difficulty sleeping, headache, sensitive skin, decreased sensation, 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
- 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 side-effects (which may affect more than 1 person in 1000):

- 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.

Since introduction to the market 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
- Inflammation of the liver, yellowing of the skin and eyes
- 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
- Blood glucose fluctuations in patients with diabetes.

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

5 HOW TO STORE GABAPENTIN TEVA

Keep out of the reach and sight of children.

Do not use Gabapentin Teva after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

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 FURTHER INFORMATION

What Gabapentin Teva contains

- The active substance is gabapentin. Each film-coated tablet contains either 600 mg or 800 mg gabapentin.
- The other ingredients in Gabapentin Teva 600 & 800 mg tablets are:
 - Core:** povidone K30, cellulose, microcrystalline, crospovidone, talc, hydrogenated vegetable (cottonseed) oil Type I
 - Coating:** hypromellose, titanium dioxide (E171), macrogol 400

What Gabapentin Teva looks like and contents of the pack

Gabapentin Teva comes in 2 different strengths of tablets which can be identified by their inscription:

600 mg: white to off-white, oval shaped, bevelled edged, film-coated tablets, engraved "7173" on one side, and "93" on the other side.

800 mg: white to off-white, oval shaped, bevelled edged, film-coated tablets, engraved "7174" on one side, and "93" on the other side.

Bottle: White, round HDPE bottle with metal cap with polyethylene liner and polystyrene pressure foam seal. The bottle contains a cylinder (with silica gel as desiccant).

Pack sizes: one bottle containing 1, 20, 30, 45, 50, 84, 90, 100, 200 or 500 film-coated tablets

Blisters:

- PVC-PE-PVdC-PE-PVC/aluminium blister
 - PVC-PE-PVdC/aluminium blister
 - aluminium/aluminium blister
- Pack sizes: 1, 20, 30, 45, 50, 84, 90, 100, 200 or 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

TEVA Pharma B.V., Computerweg 10, 3542 DR Utrecht, The Netherlands

Manufacturers

TEVA UK Ltd, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, England
TEVA Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hungary

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TEVA Design Department Harlow

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