

GABATOR CAPSULES

Gabapentin (300mg, 400 mg)

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What Gabator is used for

Epilepsy:

Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children age 3 years and above. Safety and effectiveness for adjunctive therapy in paediatric patients below the age of 3 years have not been established.

Neuropathic pain (complex, chronic pain state that usually is accompanied by tissue injury):

Gabapentin is indicated for the treatment of neuropathic pain which includes diabetic neuropathy (nerve damage that can occur if you have diabetes), post-herpetic neuralgia (persistent nerve pain and shingles (painful rash) that can occur as a result of herpes zoster virus (commonly known as chicken pox virus)) and trigeminal neuralgia (chronic, severe facial pain) in adults' age 18 years and above. Safety and effectiveness in patients below the age of 18 years have not been established.

How Gabator works

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

Before you use Gabator

- When you must not use it

Do not take Gabator:

- If you are allergic (hypersensitive) to Gabapentin or to any of the other ingredients of Gabator.

Pregnancy and lactation

Tell your doctor if you are pregnant or intend to become pregnant.

Gabator should not be taken during pregnancy, unless you are told otherwise by your doctor. Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Gabator. 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.

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

- Before you start use it

A small number of people taking Gabator 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 Gabator.

If you have kidney problems, nervous system disorders, respiratory disorders or you are more than 65 years old, your doctor may prescribe a different dosing regimen.

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.

- 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 Gabator.

If you are taking cimetidine, please tell your doctor or pharmacist as cimetidine may interfere the effect of Gabator if it is taken together.

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

Gabator is not expected to interact with other anti-epileptic drugs or the oral contraceptive pill.

How to use Gabator

- How much to use

Always take Gabator 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 Gabator is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

If you are an elderly patient (over 65 years of age), you should take the normal dose of Gabator unless you have problems with your kidneys. Continue taking Gabator until your doctor tells you to stop.

Method and route of administration

Gabator is for oral use. Always swallow the capsules or tablets whole with plenty of water. Gabator can be taken with or without food.

Epilepsy, the usual 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 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3600mg each day.

Children aged 3 – 12 years:

The starting dose should range from 10 to 15 mg/kg/day given in equally divided doses (three times a day), and the effective dose reached by upward titration over a period of approximately three days. The effective dose of gabapentin in patients age 5 years and older is 25 to 35 mg/kg/day given in equally divided doses (three times a day). The effective dose in paediatric patients ages 3 to less than 5 years is 40

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mg/kg/day given in equally divided doses (three times a day). Dosages up to 50 mg/kg/day have been well tolerated in a long-term clinical study. The maximum time interval between doses should not exceed 12 hours.

Peripheral Neuropathic Pain, the usual dose is:

Adults:

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 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3600mg each day.

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.

- When to use it

Your doctor will tell you to take the recommended dose for each treatment in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening.

If you are an elderly patient (over 65 years of age), your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

- How long to use it

Do not stop taking Gabator unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of one (1) week. If you stop taking Gabator suddenly or before your doctor tells you to, there is an increased risk of seizures.

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

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Higher than recommended doses may result in an increase in side effects

including dizziness, double vision, slurred speech, drowsiness, and diarrhea. Call your doctor or go to the nearest hospital emergency unit immediately if you take more Gabator than your doctor prescribed. Take along 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.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Gabator.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Gabapentin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or drowsiness or tired, do not drive or use machines and contact your doctor immediately.

Seizures

As with other antiseizure medicine, some people may experience an increase in seizure frequency or the onset of new types of seizures with gabapentin. If you experience the same, stop using gabapentin and contact your doctor immediately.

Respiratory depression (slow breathing)

Gabapentin has been associated with severe respiratory depression. You might be at higher risk of experiencing this severe adverse reaction if you:

- Have compromised respiratory function.
- Have respiratory or nerve related disease.
- Have kidney impairment.

- Is on concomitant use of Centre Nervous System depressants such as morphine.
- Is an elderly.

If you experience this, stop using gabapentin and contact your doctor immediately.

Abuse and dependence

If you have signs of gabapentin abuse such as drug-seeking behaviour, dose escalation and development of tolerance, please contact your doctor immediately.

Drug Rash with Eosinophilia and Systemic Symptoms (DRESS).

DRESS are severe, life-threatening, systemic hypersensitivity reactions which has been reported with gabapentin. Symptoms includes fever or lymphadenopathy (disease of the lymph nodes, in which they are abnormal in size, number, or consistency) may be present even though rash is not evident. If such signs or symptoms are present, discontinue Gabator and seek for medical care.

Kidney Problem

If you suffer from kidney problems your doctor may prescribe a different dosing schedule.

Anaphylaxis (serious, life-threatening allergic reaction).

Gabapentin can cause anaphylaxis. Signs and symptoms includes difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment. If you experience any signs or symptoms of anaphylaxis, stop using gabapentin and seek immediate medical care.

Suicidal ideation and behaviour

If you have signs of suicidal ideation and behaviours, you should seek medical care immediately.

Acute pancreatitis (inflamed pancreas).

If you develops acute pancreatitis under treatment with gabapentin, discontinuation of gabapentin should be considered.

Side effects

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

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Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine:

- Viral infection, pneumonia (lung infection), respiratory infection, urinary tract infection, otitis media (inflammation of the middle ear).
- Leucopenia (white blood cell count) decreased).
- Anorexia (lack or loss of appetite for food), increased appetite.
- Hostility (unfriendliness), confusion and emotional lability, depression, anxiety, nervousness, thinking abnormal.
- Somnolence, dizziness, ataxia (the loss of full control of bodily movements).
- Convulsions, hyperkinesia (muscle spasm), dysarthria (disorder of speech), amnesia (partial or total loss of memory), tremor, insomnia (difficult to sleep), headache, sensations such as paresthesia (burning or prickling sensation), hypaesthesia (reduced sensibility to touch), coordination abnormal, nystagmus (condition where the eyes move rapidly and uncontrollably), increased, decreased, or absent reflexes.
- Visual disturbances such as amblyopia (lazy eye, is a vision development disorder in which an eye fails to achieve normal visual acuity, even with prescription eye glasses or contact lenses), diplopia (double vision).
- Vertigo (sensation of feeling off balance).
- Hypertension, vasodilatation (dilatation of blood vessels, which decreases blood pressure).
- Dyspnoea (difficulty in breathing), bronchitis (inflammation of the airways that carry air to your lungs), pharyngitis (inflammation of the pharynx, which is in the back of the throat), cough, rhinitis (irritation and inflammation of the mucous membrane inside the nose).
- Vomiting, nausea, dental abnormalities, gingivitis (inflammation of the gums), diarrhoea, abdominal pain, dyspepsia (indigestion), constipation, dry mouth or throat, flatulence.
- Facial oedema, purpura most often described as bruises resulting from

physical, trauma, rash, pruritus (severe itching of the skin), acne.

- Arthralgia (joint pain), myalgia (muscle pain), back pain and twitching.
- Impotence.
- Fatigue, fever, peripheral oedema, abnormal gait, asthenia (lack of energy), pain, malaise (general feeling of discomfort, illness, or uneasiness whose exact cause is difficult to identify), flu syndrome.
- Accidental injury, fracture, abrasion (wound caused by superficial damage to the skin).

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you experience breathing problems such as slow, shallow or weak breathing after taking this medicine as this can be a sign of respiratory depression.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Gabator

- Storage

- Store below 30°C. Protected from moisture.

- Disposal

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.

Product Description

- What it looks like

GABATOR CAPSULES 300 MG:

Yellow/Yellow coloured, size '1', capsules printed with '300' in black colour on the cap and Torrent logo (Square emblem only) in black colour on the body of capsule shell containing white to off-white powder.

GABATOR CAPSULES 400 MG:

Orange/Orange coloured, size '0', capsules printed with '400' in black colour on the cap and Torrent logo (Square emblem only) in black colour on the body of capsule shell containing white to off-white powder.

Ingredients

Active ingredient

- Gabapentin.

Inactive ingredients

- Lactose Anhydrous.
- Starch Dried.
- Talc.
- Hard gelatin capsule size '1' yellow / yellow (for GABATOR CAPSULES 300 MG).
- Hard gelatin capsule size '0' Orange/Orange (for GABATOR CAPSULES 400 MG).

- MAL number(s):

GABATOR CAPSULES 300 MG

MAL18026162AZ

GABATOR CAPSULES 400 MG

MAL18026184AZ

Manufacturer

Torrent Pharmaceuticals LTD.
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Product Registration Holder

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