

NEURONTIN® CAPSULES

Gabapentin (Capsule: 100 mg, 300 mg & Tablet: 600 mg)

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What NEURONTIN is used for

NEURONTIN is used to treat epilepsy (seizures that are initially limited to certain parts of the brain, whether the seizure spreads to other parts of the brain or not) and peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

How NEURONTIN works

NEURONTIN 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 NEURONTIN

- When you must not use it

Do not take NEURONTIN:

- If you are allergic (hypersensitive) to gabapentin or any of the other ingredients of NEURONTIN

Pregnancy and lactation

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

NEURONTIN 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.

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

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 NEURONTIN, is passed through human milk. As the effect on the baby is unknown, caution should be exercised when gabapentin is administered to a nursing mother.

Gabapentin should be used in nursing mothers only if the benefits clearly outweigh the risks.

- Before you start to use it

Inform your doctor if you have the following:

-If you are about to take any prescription or non-prescription medications, alcohol, or drugs you are now taking or are planning to take during your treatment with gabapentin.

-NEURONTIN hard capsules contain lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

-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 NEURONTIN.

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

NEURONTIN may cause somnolence, respiratory depression, sedation and death when taken with CNS depressants including opioids, particularly in frail patients, in the elderly, in patients with serious underlying respiratory disease, with polypharmacy (concurrent use of multiple medications), and in those patients with substance abuse disorders.

NEURONTIN may interfere with some laboratory tests, if you require a urine test tell your doctor or hospital what you are taking.

How to use NEURONTIN

- How much to use

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

Method and route of administration

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

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Epilepsy, the usual dose is:

- Adults and adolescents:

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.

- Children aged 3 – 12 years:

Your doctor will prescribe a starting dose that should range from 10 to 15 mg/kg/day given in equally divided doses (three times a day), and the effective dose is reached 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 pediatric patients ages 3 to less than 5 years is 40 mg/kg/day. Dosages up to 50 mg/kg/day have been well tolerated in a long-term clinical study with a time interval between doses should not exceed 12 hours.

Peripheral Neuropathic Pain, the usual dose is:

- Adults:

Your doctor will usually build up your dose gradually. The starting dose will generally be 900 mg/day given in three equally divided doses. Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3600 mg 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.

You should not allow more than 12 hours between gabapentin doses to prevent breakthrough convulsions.

- How long to use it:

Take NEURONTIN exactly as prescribed by your doctor.

Do not suddenly stop taking NEURONTIN or reduce your dose. Discuss with your doctor first before doing so. Your doctor will tell you how to gradually reduce your dose before stopping the medicine so that any unpleasant withdrawal symptoms are kept to a minimum. This may occur over a period of weeks to months. If you stop taking NEURONTIN suddenly or before your doctor tells you to, there is an increased risk of seizures.

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

- If you forget to use it

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 use too much (overdose)

Higher than recommended doses (up to 49 g) may result in an increase in side effects including

loss of consciousness, dizziness, double vision, slurred speech, drowsiness, loss of consciousness, lethargy and diarrhoea. Call your doctor or go to the nearest hospital emergency unit immediately if you take more NEURONTIN than your doctor prescribed. Take along any capsules or 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.

While you are using it

- Things you must do

- 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.

- Things you must not do

Do not suddenly stop taking the medicine or reduce your dose unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give NEURONTIN to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Severe, life-threatening, systemic hypersensitivity reactions such as drug rash with eosinophilia and systemic symptoms (DRESS) have been reported in patients taking

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antiepileptic drugs, including gabapentin.

Inform your doctor if you have early manifestations of hypersensitivity, such as fever, lymphadenopathy (disease of the lymph nodes, in which they are abnormal in size, number, or consistency), rash or any allergic or skin reaction. If such signs or symptoms are present, report to a physician immediately. They may develop into more serious problems if they are not treated.

Early manifestations of hypersensitivity may be present even though rash is not evident.

Gabapentin has been associated with severe respiratory depression. Patients with compromised respiratory function, respiratory or neurological disease, kidney impairment, concomitant use of CNS depressants and the elderly might be at higher risk of experiencing this severe adverse reaction.

Gabapentin can cause anaphylaxis, an acute allergic reaction to an antigen to which the body has become hypersensitive. Signs and symptoms in reported cases have included difficulty breathing, swelling of the lips, throat, and tongue, and hypotension (abnormally low blood pressure) requiring emergency treatment and seek immediate medical care should they experience signs or symptoms of anaphylaxis.

Gabapentin treatment has been associated with dizziness and somnolence (drowsiness), which could increase the occurrence of accidental injury (fall).

Driving and using machines

NEURONTIN 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.

Take special care with NEURONTIN:

- 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)

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.

Side effects

Like all medicines, NEURONTIN 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)
- NEURONTIN 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 NEURONTIN.

Side effects that occurred in 10% or more of study subjects:

- Viral infection (when used in children)
- Feeling drowsy, dizziness, lack of coordination
- Fatigue, fever (when used in children)

Side effects that occurred in at least 1% (but less than 10%) of study subjects:

- Pneumonia, respiratory infections, urinary tract infection, or other infections
- Low white blood cell counts
- Anorexia (loss of appetite), increased appetite
- Anger towards others, confusion, mood changes, depression, anxiety, nervousness, difficulty with thinking
- Jerky movements, difficulty with speaking, loss of memory, tremor (involuntary muscle movement), difficulty sleeping, headache, sensitive skin, decreased sensation (numbness), difficulty with coordination, unusual eye movement, increased, decreased or absent reflexes
- Blurred vision, double vision
- Vertigo, dizziness (when used in children)
- High blood pressure, flushing or dilation of blood vessels
- Difficulty breathing, bronchitis, cough
- Vomiting (a forceful discharge of stomach contents), nausea (feeling sick with an inclination to vomit), 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,

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- 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.

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 become 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 NEURONTIN

- Storage

Keep out of the reach and sight of children.

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

Store NEURONTIN hard capsules at controlled room temperature (below 30°C). Store NEURONTIN film-coated tablets below 25°C.

- 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

Capsule, hard:

- Gabapentin 100 mg is a hard gelatin capsule with a white opaque cap, blue printed "Neurontin 100 mg" and white opaque body, blue printed "VLE".
- Gabapentin 300 mg is a hard gelatin capsule with a light yellow opaque cap, grey printed "Neurontin 300 mg" and light yellow opaque body, grey printed "VLE".

Tablet:

- Gabapentin 600 mg is a white elliptical shaped, film-coated tablets with a bisecting score on both sides and debossed with 'NT' and '16' on one side.

- Ingredients

- Active ingredient
Gabapentin
- Inactive ingredients
Each capsule also contains lactose, corn starch, talc.
Each tablet also contains poloxamer 407, copolyvidonum, corn starch, magnesium stearate, talc, hydroxypropyl cellulose, candelilla wax.

- MAL numbers

<u>Product Name</u>	<u>Registration Number</u>
NEURONTIN 100 mg Capsules	MAL06071076ARZ
NEURONTIN 300 mg Capsules	MAL19984786ARZ
NEURONTIN 600 mg Tablet	MAL20031747ARZ

Manufacturer

Viatrix Pharmaceuticals, LLC
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Product Registration Holder

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