

Neurovyx Capsule 300mg

Gabapentin (300mg)

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What Neurovyx is used for

Neurovyx 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 Neurovyx works

Neurovyx 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 Neurovyx

When you must not use it

Do not take Neurovyx if you are allergic (hypersensitive) to gabapentin or any of the other ingredients of Neurovyx.

Pregnancy and lactation

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

Neurovyx 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 Neurovyx.

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 Neurovyx, 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.
- 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 Neurovyx.

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

Neurovyx may cause somnolence (excessive sleepiness), respiratory depression (slow and ineffective breathing), 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.

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

How to use Neurovyx

How much to use

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

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Your doctor will determine what dose is appropriate for you.

If you have the impression that the effect of Neurovyx is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Method and route of administration

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

Epilepsy, the usual dose is:

Adults and adolescents: The starting dose will generally be between 300 mg (1 capsule) and 900 mg (3 capsules) 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 aged 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 (3 capsules per 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 gap between gabapentin doses to prevent breakthrough convulsions.

How long to use it

Do not stop taking Neurovyx 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 Neurovyx 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

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

diarrhea. Call your doctor or go to the nearest hospital emergency unit immediately if you take more Neurovyx 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 Neurovyx

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 stop taking the medicine unless advised by your doctor.

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

Do not give Neurovyx 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 antiepileptic drugs, including gabapentin.

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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 or operating machinery

Neurovyx 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.

Take special care with Neurovyx if you:

- Suffer from kidney problems your doctor may prescribe a different dosing schedule.
- Are on haemodialysis (to remove waste products because of kidney failure), tell your doctor if you develop muscle pain and/or weakness.
- 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, Neurovyx 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).
- Neurovyx 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 Neurovyx.

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 count.
- 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,

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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.

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.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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 Neurovyx

Storage

Store below 30°C.

Keep Neurovyx out of the reach and sight of children.

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

A size #1 yellow colour cap and body hard gelatin capsule, containing white powder.

Ingredients

- Active ingredient:
Gabapentin.
- Inactive ingredients:
Microcrystalline cellulose,
Pregelatinized starch,
Sodium lauryl sulfate and
Magnesium stearate.

MAL number

MAL24126029AZ

Manufacturer and Product Registration Holder

Y.S.P. Industries (M) Sdn. Bhd.
Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru
Bangi, 43000 Kajang, Selangor, Malaysia.

Date of revision

02/03/2026

Serial Number

NPRA (R2) 24/076.