

PACKAGE LEAFLET: INFORMATION FOR THE USER

NIRVAX

300 mg capsules

GABAPENTIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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2. Before you take NIRVAX
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1. WHAT NIRVAX IS AND WHAT IS IT USED FOR

NIRVAX Capsules belong to a group of medicines used to treat epilepsy and peripheral neuropathic pain.

Epilepsy: NIRVAX Capsules are 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 NIRVAX Capsules for you to help treat your epilepsy when your current treatment is not fully controlling your condition.

You should take NIRVAX Capsules in addition to your current treatment unless told otherwise.

NIRVAX Capsules can also be used on its own to treat adults and children over 12 years of age.

Peripheral neuropathic pain: NIRVAX Capsules are used to treat long-lasting pain caused by damage to the nerves. A variety of different diseases can cause peripheral (primarily occurring in the legs and/or arms) neuropathic pain, 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 NIRVAX

Do not take NIRVAX Capsules

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

Important information about potentially serious reactions

A small number of people taking NIRVAX Capsules 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 NIRVAX Capsules.

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'.

Warnings and precautions

Talk to your doctor or pharmacist before taking NIRVAX Capsules

- if you suffer from kidney problems
- 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.

Other medicines and NIRVAX Capsules

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 NIRVAX Capsules.

NIRVAX Capsules are not expected to interact with other antiepileptic drugs or the oral contraceptive pill.

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

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

NIRVAX Capsules with food and drink

NIRVAX Capsules can be taken with or without food.

Pregnancy and breastfeeding

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

NIRVAX Capsules 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 and only under the advice of your doctor, you should try to take only one seizure medication during pregnancy.

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 NIRVAX Capsules.

Gabapentin, the active substance of NIRVAX Capsules, is excreted in human milk.

Because the effect on the nursing infant is unknown, it is not recommended to breast-feed your baby while using NIRVAX Capsules.

Driving and using machines

NIRVAX Capsules 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.

NIRVAX Capsules contain lactose.

If you have been told by your doctor that you have an intolerance to some sugars. Contact your doctor before taking this medicinal product.

3. HOW TO TAKE NIRVAX

Always take NIRVAX Capsules 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 NIRVAX Capsules 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 NIRVAX Capsules normally except if you have problems with your kidneys.

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

Always swallow the capsules whole with plenty of water.

Continue taking NIRVAX Capsules until your doctor tells you to stop.

Peripheral Neuropathic Pain:

Take the number of capsules 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 stepwise up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening.

Epilepsy

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 stepwise up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 divided 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/kg/day. It is usually given in 3 divided doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.

NIRVAX Capsules are not recommended for use in children below 6 years of age.

If you take more NIRVAX Capsules than you should

Call your doctor or go to the nearest hospital emergency unit immediately. Take along any capsules that are left, the container and the label so that the hospital can easily tell what medicine you have taken.

If you forget to take NIRVAX Capsules

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 NIRVAX Capsules

Do not stop taking NIRVAX Capsules 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 NIRVAX Capsules 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 NIRVAX Capsules 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.

NIRVAX Capsules 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 a rash when you get this type of reaction. It may cause you to be hospitalized or to stop NIRVAX Capsules.

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
- unusual bruising or bleeding
- yellowing of your skin or of the whites of the eyes
- 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 NIRVAX Capsules.

Very common: may affect more than 1 in 10 people

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

Common: may affect up to 1 in 10 people

- Pneumonia, respiratory infection, urinary tract infection, infection, 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
- Incontinence
- Difficulties with erection
- Swelling in the legs and arms or swelling that may involve the face, trunk and limbs, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
- Decrease in white blood cells, increase in weight
- Accidental injury, fracture, abrasion.

Rare: may affect up to 1 in 1,000 people

- Decreased platelets (blood clotting cells)
- Allergic reaction such as hives
- Hallucinations
- Problems with abnormal movements such as writhing, jerking movements and stiffness
- Ringing in the ears
- Racing heartbeat
- Inflammation of the pancreas

- Inflammation of the liver, yellowing of the skin and eyes
- Acute kidney failure
- Severe skin reactions that require immediate medical attention, swelling of the lips and face, skin rash and redness, hair loss
- Adverse events following the abrupt discontinuation of gabapentin (anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
- Blood glucose fluctuations in patients with diabetes, abnormal blood test results suggesting problems with the liver.

Additionally in clinical studies in children, aggressive behaviour and jerky movements were reported commonly.

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

5. HOW TO STORE NIRVAX

Keep out of the reach and sight of children.

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

You should store your medicine below 25°C.

Store in the original package.

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.