

NEUROMED[®] 75 mg NEUROMED[®] 150 mg

Capsules

PREGABALINE

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, pharmacist or nurse.
- 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 like yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What NEUROMED[®] is and what it is used for
2. What you need to know before you take NEUROMED[®]
3. How to take NEUROMED[®]
4. Possible side effects
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1. What NEUROMED[®] is and what it is used for

NEUROMED[®] belongs to a group of medicines used to treat epilepsy, neuropathic pain and Generalised Anxiety Disorder (GAD) in adults.

Indications:

- Neuropathic pain: NEUROMED[®] is used to treat Peripheral and central neuropathic Pain
- Epilepsy: NEUROMED[®] is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation) in adults
- Generalised Anxiety Disorder: NEUROMED[®] is used to treat Generalised Anxiety Disorder (GAD) in adults.

2. What you need to know before you take NEUROMED[®]

Do not take NEUROMED[®]:

If you are allergic to pregabalin or any of the other ingredients of this medicine (listed in section 6).

Warnings and Precautions

Some patients taking NEUROMED[®] have reported symptoms suggesting an allergic reaction. These symptoms include swelling of the face, lips, tongue, and throat, as well as diffuse skin rash. Should you experience any of these reactions, you should contact your physician immediately.

NEUROMED[®] has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in elderly patients. Therefore, you should be careful until you are used to taking the medicine.

NEUROMED[®] may cause blurring or loss of vision, or other changes in eyesight, many of which are temporary. You should immediately tell your doctor if you experience any changes in your vision.

Some patients with diabetes who gain weight while taking pregabalin may need an alteration in their diabetic medicines. Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to Pregabalin and the severity of these effects may be increased when taken together.

There have been reports of heart failure in some patients when taking NEUROMED[®]; these patients were mostly elderly with cardiovascular conditions. Before taking this medicine you should tell your doctor if you have a history of heart disease. There have been reports of kidney failure in some patients when taking NEUROMED[®]. If while taking NEUROMED[®] you notice decreased urination, you should tell your doctor or stopping the medicine may improve this.

A small number of people being treated with anti-epileptics such as NEUROMED[®] have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

When NEUROMED[®] is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g. constipation, bloated or paralysed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.

Before taking this medicine you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence. Do not take more medicine than prescribed.

There have been reports of convulsions when taking NEUROMED[®] or shortly after stopping NEUROMED[®]. If you experience a convulsion, contact your doctor immediately.

There have been reports of reduction in brain function (encephalopathy) in some patients taking NEUROMED[®] when they have other conditions. Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease.

Children and adolescents

The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, pregabalin should not be used in this age group.

Other medicines and NEUROMED[®]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. NEUROMED[®] and certain other medicines may influence each other (interaction). When taken with certain other medicines, NEUROMED[®] may potentiate the side effects seen with these medicines, including respiratory failure and coma. The degree of dizziness, sleepiness and decreased concentration may be increased if NEUROMED[®] is taken together with medicines containing:

- Oxycodone – (used as a pain killer)
- Lorazepam – (used for treating anxiety)
- Alcohol

NEUROMED[®] may be taken with oral contraceptives.

NEUROMED[®] with food, drink and alcohol

NEUROMED[®] capsules may be taken with or without food.

It is advised not to drink alcohol while taking NEUROMED[®].

Pregnancy and breast-feeding

NEUROMED[®] should not be taken during pregnancy or when breast-feeding, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

NEUROMED[®] may produce dizziness, sleepiness and decreased concentration. You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

NEUROMED[®] contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

How to take NEUROMED[®]

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will determine what dose is appropriate for you. NEUROMED[®] is for oral use only.

Peripheral and central neuropathic pain, epilepsy or Generalised Anxiety Disorder:

- Take the number of capsules as instructed by your doctor.
- The dose, which has been adjusted for you and your condition, will generally be between 150 mg and 600 mg each day.
- Your doctor will tell you to take NEUROMED[®] either twice or three times a day.
- For twice a day take NEUROMED[®] once in the morning and once in the evening, at about the same time each day.
- For three times a day take NEUROMED[®] once in the morning, once in the afternoon and once in the evening, about the same time each day.

If you have the impression that the effect of NEUROMED[®] 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 NEUROMED[®] 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.

Swallow the capsule whole with water.

Continue taking NEUROMED[®] until your doctor tells you to stop.

If you take more NEUROMED[®] than you should

Call your doctor or go to the nearest hospital or emergency unit immediately. Take your box or bottle of NEUROMED[®] capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more NEUROMED[®] than you should. Fits have also been reported.

If you forget to take NEUROMED[®]

It is important to take your NEUROMED[®] capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take

a double dose to make up for a forgotten dose.

If you stop taking NEUROMED[®]

Do not stop taking NEUROMED[®] unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week.

After stopping long and short term NEUROMED[®] treatment, you need to know that you may experience certain side effects. These include, trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, pain, sweating, and dizziness. These symptoms may occur more commonly or severely if you have been taking NEUROMED[®] for a longer period of time.

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

4. Possible side effects

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

Very common: may affect up to 1 in 10 people

Dizziness, drowsiness, headache.
Common: may affect up to 1 in 10 people

- Increased appetite.
- Feeling of elation, confusion, disorientation, decrease in sexual interest, irritability.
- Disturbance in attention, clumsiness, memory impairment, loss of memory, tremor, difficulty with speaking, tingling feeling, numbness, sedation, lethargy, insomnia, fatigue, feeling abnormal.
- Blurred vision, double vision.
- Vertigo, problems with balance, fall.
- Dry mouth, constipation, vomiting, flatulence, diarrhoea, nausea, swollen abdomen.
- Difficulties with erection.
- Swelling of the body including extremities.
- Feeling drunk, abnormal style of walking.
- Weight gain.
- Muscle cramp, joint pain, back pain, pain in limb.
- Sore throat.

Uncommon: may affect up to 1 in 100 people

- Loss of appetite, weight loss, low blood sugar, high blood sugar.
- Change in perception of self, restlessness, depression, agitation, mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attack, apathy, aggression, elevated mood, mental impairment, difficulty with thinking, increase in sexual interest, problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation.
- Changes in eyesight, unusual eye movement, changes in vision including tunnel vision, flashes of light, jerky movements, reduced reflexes, increased activity, dizziness on standing, sensitivskin, loss of taste, burning sensation, tremor on movement, decreased consciousness, loss of consciousness, fainting, increased sensitivity to noise, feeling unwell.
- Dry eyes, eye swelling, eye pain, weak eyes, watery eyes, eye irritation.
- Heart rhythm disturbances, increased heart rate, low blood pressure, high blood pressure, changes in heart beat, heart failure.

• Flushing, hot flashes.

• Difficulty breathing, dry nose, nasal congestion.

• Increased saliva production, heartburn, numb around mouth.

• Sweating, rash, chills, fever.

• Muscle twitching, joint swelling, muscle stiffness, pain including muscle pain, neck pain.

• Breast pain.

• Difficulty with or painful urination, incontinence.

• Weakness, thirst, chest tightness.

• Changes in blood and liver test results (blood creatinine phosphokinase increased, alanine aminotransferase increased, aspartate aminotransferase increased, platelet count decreased, neutropenia, increase in blood creatinine, decrease in blood potassium).

• Hypersensitivity, swollen face, itchiness, hives, runny nose, nose bleed, cough, snoring.

• Painful menstrual periods.

• Coldness of hands and feet.

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

• Abnormal sense of smell, swinging vision, altered perception of depth, visual brightness, vision loss.

• Dilated pupils, cross eyes.

• Cold sweat, tightness of the throat, swollen tongue.

• Inflammation of the pancreas.

• Difficulty in swallowing.

• Slow or reduced movement of the body.

• Difficulty with writing properly.

• Increased fluid in the abdomen.

• Fluid in the lungs.

• Convulsions.

• Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances.

• Muscle damage.

• Breast discharge, abnormal breast growth, breast growth in males.

• Interrupted menstrual periods.

• Kidney failure, reduced urine volume, urinary retention.

• Decrease in white blood cell count.

• Inappropriate behaviour.

• Allergic reactions (which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction characterized by rash, blisters, peeling skin and pain).

• Jaundice (yellowing of the skin and eyes).

If you experience swollen face or tongue or if your skin turns red and starts to blister or peel, you should seek immediate medical advice.

Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to Pregabalin and the severity of these effects may be increased when taken together.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store NEUROMED[®]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or bottle. 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.

Shelf life: 2 years.

This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What NEUROMED[®] contains

	NEUROMED [®] 75 mg	NEUROMED [®] 150 mg
Active substance :	75 mg	150 mg
Pregabalin		
Excipients :		
Lactose monohydrate, maize starch , talc		

What NEUROMED[®] looks like and contents of the pack

NEUROMED[®] 75 mg, capsules. They are supplied in pack size of 15 and 30 per pack.

NEUROMED[®] 150 mg, capsules. They are supplied in pack size of 30 and 90 per pack.

Marketing authorisation holder and manufacturer

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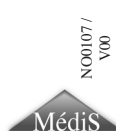
MARKETING AUTHORISATION NUMBER(S):

This leaflet was last approved in:

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children



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