

Neurogab

Pregabalin Capsules (75mg, 150mg)

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1. What Neurogab is used for:

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

Peripheral and central neuropathic pain:

Neurogab is used to treat long lasting pain caused by damage to the nerves. A variety of diseases can cause peripheral 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. Peripheral and central neuropathic pain may also be associated with mood changes, sleep disturbance, fatigue (tiredness), and can have an impact on physical and social functioning and overall quality of life.

Epilepsy:

Neurogab is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation) in adults. Your doctor will prescribe Neurogab for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take Neurogab in addition to your current treatment. Neurogab is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalised Anxiety Disorder:

Neurogab is used to treat Generalised Anxiety Disorder

(GAD). The symptoms of GAD are prolonged excessive anxiety and worry that are difficult to control. GAD can also cause restlessness or feeling keyed up or on edge, being easily fatigued (tired), having difficulty concentrating or mind going blank, feeling irritable, having muscle tension or sleep disturbance. This is different to the stresses and strains of everyday life.

2. How Neurogab works:

Neurogab belongs to a group of medicines called anticonvulsants. Neurogab works in different ways: in epilepsy it stops seizures by reducing the abnormal electrical activity in the brain, with nerve pain it blocks pain by interfering with pain messages travelling through the brain and down the spine.

3. Before you use Neurogab:

- When you must not use it

If you are allergic to Neurogab or any of the other ingredients of this medicine.

- Before you start to use it

Talk to your doctor or pharmacist before taking Neurogab.

- Some patients taking Neurogab 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.
- Neurogab 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 any effect the medicine might have.
- Neurogab 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 Neurogab 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 Neurogab and the severity of these effects may be increased when taken together.
- There have been reports of heart failure in some patients when taking Neurogab; 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 Neurogab. If while taking Neurogab you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.

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

When Neurogab 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, blocked 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.

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There have been reports of convulsions when taking Neurogab or shortly after stopping Neurogab. If you experience a convulsion, contact your doctor immediately. There have been reports of reduction in brain function (encephalopathy) in some patients taking Neurogab when they have other conditions. Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Neurogab and certain other medicines may influence each other (interaction). When taken with certain other medicines which have sedative effects (including opioids), Neurogab may potentiate these effects, and could lead to respiratory failure, coma and death. The degree of dizziness, sleepiness and decreased concentration may be increased if Neurogab is taken together with medicines containing:

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

Neurogab may be taken with oral contraceptives.

4. How to use Neurogab:

- How much to use

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.

Neurogab 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 Neurogab either twice or three times a day. For twice a day take Neurogab once in the morning and once in the evening, at about the same time each day. For three times a day take Neurogab once in the morning, once in the afternoon and once in the evening, at about the same time each day.

- When to use it

If you have the impression that the effect of Neurogab 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 Neurogab 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.

- How long to use it

Continue taking Neurogab until your doctor tells you to stop.

- If you forget to use it

It is important to take your Neurogab 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 Neurogab

Do not stop taking Neurogab 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 Neurogab treatment, you need to know that you may experience certain side effects. These include,

trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flulike symptoms, convulsions, nervousness, depression, pain, sweating, and dizziness. These symptoms may occur more commonly or severely if you have been taking Neurogab for a longer period of time.

- If you use too much (overdose)

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

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

5. While you are using it:

- Things you must do

Neurogab capsules may be taken with or without food.

- Things you must not do

Driving and using machines:

Neurogab 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.

Children and adolescents:

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

Neurogab with Alcohol:

It is advised not to drink alcohol while taking Neurogab.

- Things to be careful of:

Pregnancy and breast-feeding

Neurogab 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.

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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.

6. Side Effects

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

Very common: may affect more than 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, sensitive skin, 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 flushes.
- 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 amino transferase increased, aspartate aminotransferase increased, platelet count decreased, neutropaenia, 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.
- 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).

Very rare: may affect up to 1 in 10,000 people

- Liver failure.
- Hepatitis (inflammation of the liver).

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 Neurogab 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.

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

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

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

7. Storage and Disposal of Neurogab

- Storage

Do not store above 30°C.

Keep out of sight and reach 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.

8. Product Description

What it looks like and contents of the pack

Neurogab 75: Brown/White size '4' hard gelatin capsules imprinted with 'M3' on cap and '75mg' on body containing white coloured powder.

Neurogab 150: White/white, size "2", hard gelatin capsules imprinted with "M5" on cap and " 150 mg " on body containing white coloured powder.

What Neurogab contains

- *Active ingredient:* Pregabalin
- *Inactive ingredients:*
Lactose Monohydrate,
Pregelatinized Starch, Talc,
Empty hard gelatin capsule shell
contains following ingredients:
Titanium Dioxide, Gelatin, Water
and Sodium Lauryl Sulfate.

-MAL No:

Neurogab 75: MAL23106011AZ

Neurogab 150: MAL25086014AZ

9. Manufacturer and Product Registration Holder:

Manufactured By:

Macleods Pharmaceuticals Ltd.

Block N-2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, District Solan, Himachal Pradesh- 174101, India.

Office address: 304 - Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai - 400 059.

Product Registration Holder:

Macleods Pharmaceutical Sdn.

Bhd.,

A2-27-1 Soho Suites KLCC, Jalan Perak, 50450 Kuala Lumpur, Malaysia

10. Date of revision:

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