

Neurogab 75

Pregabalin Capsules 75mg

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What Neurogab 75 is used for:

Neurogab 75 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 75 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 75 is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation) in adults. Your doctor will prescribe Neurogab 75 for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take Neurogab 75 in addition to your current treatment. Neurogab 75 is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalised Anxiety Disorder: Neurogab 75 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.

How Neurogab 75 works:

Neurogab 75 belongs to a group of medicines called anticonvulsants. Neurogab 75 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.

Before you use Neurogab 75:

- When you must not use it

If you are allergic to Neurogab 75 or any of the other ingredients of this medicine.

- Before you start to use it

Talk to your doctor or pharmacist before taking Neurogab 75.

- Some patients taking Neurogab 75 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 75 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 75 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 75 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 75 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 75; 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 75. If while taking Neurogab 75, 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 75 have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

When Neurogab 75 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

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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 Neurogab 75 or shortly after stopping Neurogab 75. If you experience a convulsion, contact your doctor immediately. There have been reports of reduction in brain function (encephalopathy) in some patients taking Neurogab 75 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 75 and certain other medicines may influence each other (interaction). When taken with certain other medicines which have sedative effects (including opioids), Neurogab 75 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 75 is taken together with medicines containing:

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

Neurogab 75 may be taken with oral contraceptives.

How to use Neurogab 75:

- How much to use

- Take Neurogab exactly as prescribed. Your healthcare provider will tell you how much Neurogab to take.
- Neurogab may be taken with or without food.
- Your healthcare provider may change your dose. Do not change your dose without talking to your

healthcare provider.

- The dose range is 150 to 600 mg per day given in either two or three divided doses.

- When to use it

Take Neurogab exactly as prescribed. Your healthcare provider will tell you when to take Neurogab. It is advised to take Neurogab at the same time each day.

- How long to use it

Do not stop taking Neurogab without checking with your healthcare provider. If you stop taking Neurogab suddenly, you may have trouble sleeping, nausea, headaches, anxiety, excessive sweating, and diarrhea. If you have epilepsy and you stop taking Neurogab suddenly, you may have seizures more often.

If Neurogab is discontinued, taper the drug gradually over a minimum of 1 week rather than discontinue the drug abruptly. Talk with your healthcare provider about how to stop Neurogab slowly.

- If you forget to use it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. Do not take two doses at the same 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 Pregabalin capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more Neurogab 75 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.

While you are using it:

- Things you must do

Stop taking Neurogab 75 and call your healthcare provider

immediately if you have any of these signs of a serious allergic reaction:

- Swelling of your face, mouth, lips, gums, tongue, throat or neck
- Trouble breathing
- Rash, hives (raised bumps) or Blisters

Call your healthcare provider immediately if you have any of these symptoms, especially if they are new, worse or worry you:

- Thoughts about suicide or dying
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling agitated or restless
- Panic attacks
- Trouble sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking (mania)
- Other unusual changes in behavior or mood

- Things you must not do

- Do not drive a car, work with machines, or do other dangerous activities until you know how Neurogab affects you.

Pregabalin may cause dizziness and extreme sleepiness which may impair the ability to perform tasks such as driving or operating machinery and could increase the occurrence of accidental injury (fall) in the elderly population. Ask your healthcare provider about when it will be okay to do these activities.

- Things to be careful of:

If you have suicidal thoughts or actions, do not stop Neurogab 75 without first talking to a healthcare provider.

- Stopping Neurogab 75 suddenly can cause serious problems
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

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How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

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.

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).

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.

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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 75 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.

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)].

Storage and Disposal of Neurogab 75

- 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.

Product Description

What it looks like and contents of the pack

Brown/white, size “4”, hard gelatin capsules imprinted with “M3” on cap and “75 mg” on body containing white coloured powder.

What Pregabalin Capsules 75mg 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: MAL23106011AZ

Manufacturer

Macleods Pharmaceuticals Ltd.
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Product Registration Holder

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