

NOVUGAB CAPSULES

Pregabalin 50mg, 75mg, 150mg

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What Novugab is used for

Novugab is used to treat:

Neuropathic pain

Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy

Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Generalised anxiety disorder

Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

Fibromyalgia

Pregabalin is indicated for the management of fibromyalgia.

How Novugab works

Novugab helps decrease the number of nerve signals, and as a result calms down overly sensitive nerve cells.

Before you use Novugab

– When you must not use it

Do not start taking Novugab if you are allergic to pregabalin or any of the ingredients in Novugab. See the end of this leaflet for a complete list of ingredients in Novugab.

Symptoms of an allergic reaction to Novugab may include:

- Serious, even life-threatening allergic reactions
- Suicidal thoughts or actions
- Swelling of your hands, legs and feet
- Dizziness and sleepiness

– Before you start to use it

Tell your healthcare provider about all your medical conditions including if you:

- have or had depression, mood problems or suicidal thoughts or behavior
- have kidney problems or get kidney dialysis
- have heart problems including heart failure
- have a bleeding problem or a low blood platelet count
- have abused prescription medicines, street drugs, or alcohol in the past
- have ever had swelling in your face, mouth, tongue, lips, gums, neck or throat (angioedema)
- have brain malfunction (encephalopathy)
- cases of misuse, abuse and dependence have been reported
- caution should be exercised in patients with a history of substance abuse and the patient should be monitored for symptoms of pregabalin misuse, abuse or dependence (drug seeking behavior)
- patients undergoing treatment of central neuropathic pain due to spinal cord injury.
- **are pregnant or plan to become pregnant. It is not known if Novugab will harm your unborn baby.** You and your healthcare provider will have to decide if you should take Novugab while you are pregnant
- **are breastfeeding. Novugab is excreted in the milk of lactating women. As the safety of Novugab in infants is unknown, breast-feeding is not recommended during treatment with Novugab.** You and your healthcare provider should discuss whether you should take Novugab or breast-feed, but you should not do both.

– Taking other medicines

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins or herbal supplements. Novugab and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- Angiotensin converting enzyme (ACE) inhibitors, which are used to treat many conditions, including high blood pressure. You may have a higher chance for swelling and hives if these medicines are taken with Novugab.
- Avandia (rosiglitazone), Avandamet (contains rosiglitazone and metformin), or Actos (pioglitazone) for diabetes. You may have a higher chance of weight gain or swelling of your hands or feet if these medicines are taken with Novugab.
- Any medicines that made you sleepy
- Novugab may increase the effects of ethanol and lorazepam.
- Novugab appears to increase certain effects (impairment of thought process and gross bodily movements) caused by oxycodone.
- There are reports of lung failure and coma in patients taking Novugab and other central nervous system depressant medications.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist each time you get a new medicine. Do not start a new medicine without talking with your healthcare provider.

How to use Novugab

– How much to use

Take Novugab exactly as your doctor has prescribed. The recommended dose is to take:

- Novugab may be taken with or without food.
- Novugab is for oral use only.
- Neuropathic pain: start at a dose of 150mg per day. The dosage may be increased to 300mg per day after an interval of 3 to 7 days, and if needed, to a maximum dose of 600mg per day after an additional 7-day interval.
- Fibromyalgia: 300-450mg per day given in two divided doses.
- Epilepsy: start with a dose of 150mg per day, increased to 300mg per day after 1 week, maximum 600mg per day.
- Generalized anxiety disorder: dose range is 150 to 600mg per day given as two or three divided

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Pregabalin 50mg, 75mg, 150mg doses.

– When to use it

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

– How long to use it

Do not stop taking Novugab without checking with your healthcare provider. If you stop taking Novugab suddenly you may have headaches, nausea, diarrhoea or trouble sleeping. If you have epilepsy and you stop taking Novugab suddenly, you may have seizures more often. Talk with your healthcare provider about how to stop Novugab 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)

If you take too much Novugab, call your healthcare provider or poison control center, or go to the nearest emergency room right away.

These side effects were reported when Novugab was taken too much: Affective disorder, (disturbance of mood), sleepiness, confusion, depression, agitation and restlessness.

Fits (seizures) were also reported when the medicine was taken in overdose.

While you are using it

– Things you must do

Stop taking Novugab 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 Novugab affects you. 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 Novugab without first talking to a healthcare provider.

- Stopping Novugab 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.

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

Very Common:

- Dizziness, sleepiness
- Headache

Common:

- Cold
- Increased appetite
- Elevated mood, confused state, irritability, depression, loss in sense of direction, inability to sleep, reduced sex drive
- Lack of voluntary coordination of muscle, loss in control of posture, muscle contraction, speech disorder, loss of memory, memory impairment, disturbance in attention, abnormal tingling and pricking sensation, reduced sense of touch, relaxed state/reduction of irritability or agitation, balance disorder, lack of energy
- Blurry vision and double vision
- Loss of balance
- Nausea, vomiting, constipation or hard bowels, diarrhoea, accumulation of gas in alimentary canal, accumulation of gas or air in the abdomen, dry mouth
- muscle cramp, joint pain, back pain, pain in the limbs, tightening of muscles;
- Accumulation of fluid in tissues, abnormal walking, fall, feeling drunk, feeling abnormal, weakness
- Increased weight

If you have diabetes, you should pay attention to your skin while taking Novugab and tell your healthcare provider about any sores or skin problems.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of Novugab. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects.

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 Novugab

– Storage

Store Novugab capsules below 30°C.

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Keep in a cool, dry place away from sunlight.

– Disposal

Safely throw away any Novugab that is out of date or no longer needed

Keep Novugab and all medicines out of the reach of children.

Product Description

– What it looks like

50 mg capsules

White to off-white powder filled in size ‘4’ hard gelatin capsule, printed with ‘P 50’ on white body and ‘N’ on white cap in black ink.

75 mg capsules

White to off-white powder filled in size ‘4’ hard gelatin capsule, printed with ‘P 75’ on white body and ‘N’ on red cap in black ink.

150 mg capsules

White to off-white powder filled in size ‘2’ hard gelatin capsule, printed with ‘P 150’ on white body and ‘N’ on white cap in black ink.

– Ingredients

– Active ingredient: Pregabalin

– Inactive ingredient

List of excipients: Capsule content: Pregelatinized Starch, Talc.

Capsule shell: gelatin, purified water, titanium dioxide, iron oxide black (75mg), iron oxide yellow (75mg), iron oxide red (75mg)

Printing Ink: Shellac, Propylene Glycol, Black Iron Oxide.

– MAL number

Novugab 50mg Capsules

MAL21046036AZ

Novugab 75mg Capsules

MAL21046035AZ

Novugab 150mg Capsules

MAL21046034AZ

Route of administration: Oral

Source/Origin of gelatin: Bovine

Manufacturers

Novugen Pharma Sdn. Bhd.
No. 27, Jalan Lengkok Teknologi
2, Taman Teknologi Enstek Fasa
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Negeri Sembilan, Malaysia.

Product Registration Holder

Novugen Pharma Sdn. Bhd.
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14/11/2022

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