

GABENIL CAPSULES

Gabapentin (300mg, 400mg)

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What Gabenil is used for

- 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).
- Peripheral neuropathic pain (the long-lasting pain caused by damaged to the nerves). A variety of different diseases can cause peripheral neuropathic pain (primarily occurring in the legs and/or arms), such as diabetes or shingles.

How Gabenil works

Gabenil belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

Before you use Gabenil

- When you must not use it

If you are allergic to gabapentin or any of the other ingredients of Gabenil.

- Before you start to use it

Talk to your doctor or pharmacist before taking Gabenil if you:

- Have history of psychotic episodes
- Suffer from kidney problem

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.

You might experience mood and behavioral change or have had thoughts of harming or killing yourself, immediately contact your doctor.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have been recently taking any medicines, including medicines obtained without a prescription.

If you are taking any medicines containing morphine, please tell your doctor or pharmacist as opioids may increase the effect of Gabenil.

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

Gabenil is not expected to interact with other antiepileptic drugs or the oral contraceptive pill. It may interfere with some laboratory tests, if you require a urine test tell your doctor or hospital what you are taking.

How to use Gabenil

- How much to use

Adults:

The starting dose is 300mg given three equally divided dose and may be increased progressively up to a maximum of 3600mg each day.

Children:

The dose to be given to your child will be decided by your doctor as it is calculated against your child's weight.

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

- When to use it

Gabenil is usually given in 3 separate doses with or without food, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.

- How long to use it

You should take this medicine as long as your doctor instructed you to.

- If you forget to use it

Take the next dose as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Higher than recommended doses may result in an increase in side effects including loss of consciousness, dizziness, double

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vision, slurred speech, drowsiness and diarrhea.

Contact your doctor or nearest hospital emergency unit immediately. Take the container and any remaining tablets with you.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Gabenil.

Contact your doctor immediately if you become pregnant, think you might be pregnant or planning to become pregnant while taking Gabenil.

- Things you must not do

If you are pregnant, do not suddenly discontinue taking this medicine as this may lead to a sudden occurrence of seizure, which could have serious consequences for you and your baby.

- Things to be careful of

Do not drive, operate complex machinery or take part in other potentially hazardous activities until you know whether this medication affects your ability to perform these activities because Gabenil may produce dizziness, drowsiness and tiredness.

Side effects

Like all medicines, this medicine 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:

- Severe skin reactions that require immediate attention, swelling of the lips and face, skin rash and redness, and/ or hair loss (these may be symptoms of a serious allergic reaction)
- Persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas)
- Gabenil may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your live or blood cells.

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
- Yellowing of your skin or of the whites of the eyes
- Unusual bruising or bleeding
- 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 Gabenil.

- If you are on haemodialysis, tell your doctor if you develop muscle pain and/ or weakness.

Other side effects include:

Very common side-effects

- Respiratory infection, urinary tract infection, inflammation of the ear or other infections
- Anorexia, change of appetite

- Anger towards others, confusion, depression, anxiety, nervousness, difficulty with thinking
- Convulsions, difficulty with speaking, loss of memory, tremor, difficulty sleeping, headache, sensitive skin, decreased sensation (numbness), difficulty with coordination, unusual eye movement, increased or decreased or absent reflexes
- Blurred vision, double vision
- Dizziness
- High blood pressure, flushing or dilation of blood vessels
- Difficulty breathing, bronchitis (inflammation of the tubes that carry air to and from the lungs), sore throat, cough, dry nose
- Vomiting, nausea, problems with teeth, inflamed gum, diarrhea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
- Facial swelling, bruises, rash, itch, acne
- Joint pain, muscle pain, back pain, twitching
- Difficulties with erection (impotence)
- Swelling in the legs and arms, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
- Increase in weight

Uncommon side-effects:

- Allergic reactions such as hives
- Decreased movement
- Racing heartbeat
- Swelling that may involve the face and limbs
- Abnormal blood test results suggesting problems with liver

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

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Storage and Disposal of Gabenil

- Storage

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. The expiry date refers to the last day of that month.

Store below 30°C. Protect from light and moisture.

- Disposal

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

- Inactive ingredients
Lactose, Maize starch, Talc,
Quinoline Yellow, Erythrosin-
FD&C Red 3, Titanium Dioxide,
Gelatin.

- MAL number:

Gabenil 300:
MAL09042396AZ

Gabenil 400:
MAL09042551AZ

Manufacturer

Remedica Ltd., Ahamon Str.
Limassol Industrial Estate,
P.O. Box 51706,
3056 Limassol,
Cyprus, EU

Product Description

- What it looks like

Gabenil 300:
Hard gelatin yellow/yellow
capsules of size 1, containing
gabapentin in white to off-white
crystalline powder.

Gabenil 400:
Hard gelatin orange/orange
capsules of size 0, containing
gabapentin in white to off-white
crystalline powder.

- Ingredients

- Active ingredient
Gabenil 300:
The active ingredient is
gabapentin 300mg.

Gabenil 400:
The active ingredient is
gabapentin 400mg.

Product Registration Holder

Eucogen Sdn. Bhd.
No. 6A, Jalan Sungai Burung U32/U,
Bukit Rimau,
Seksyen 32,
40460 Shah Alam

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04/07/2019

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