

GABOTON®CAPSULE

Gabapentin (300 mg)

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WHAT GABOTON IS USED FOR

Epilepsy: GABOTON is used in the treatment of partial seizure (confine to a small part of the brain) with and without secondary generalization (seizures that spread to both sides of the brain). Your doctor will prescribe GABOTON for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take GABOTON in addition to your current treatment unless told otherwise. GABOTON can also be used on its own to treat adults and children over 6 years of age.

Peripheral neuropathic pain:

GABOTON is used to treat long lasting pain caused by damage to the nerves in adults aged 18 years and above. A variety of different diseases can cause peripheral (primarily occurring in the legs and/or arms) 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 etc.

HOW GABOTON WORKS

GABOTON belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain. Exactly how it works is not known.

BEFORE YOU USE GABOTON

When you must not use it

- if you are allergic (hypersensitive) to gabapentin or any of the other

ingredients of GABOTON.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

GABOTON should not be taken during pregnancy, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential.

There have been no studies specifically looking at the use of gabapentin in pregnant women, but other medications used to treat seizures have reported an increased risk of harm to the foetus, particularly when more than one seizure medication is taken at the same time. Therefore, whenever possible and only under the advice of your doctor, you should try to take only one seizure medication during pregnancy.

Do not suddenly discontinue taking this medicine as this may lead to breakthrough seizure, which could have serious consequences for you and your baby.

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

Gabapentin, the active substance of GABOTON is excreted in human milk. Because the effect on the nursing infant is unknown, it is not recommended to breast-feed your baby while using GABOTON

Before you start to use it

You should check with your doctor BEFORE taking GABOTON if you:

- have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.
- if you suffer from kidney problems

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

GABOTON is not expected to interact with other antiepileptic drugs or the oral contraceptive pill.

GABOTON may interfere with some laboratory tests, if you require a urine test tell your doctor or hospital that you are taking GABOTON

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

HOW TO USE GABOTON?

How much to use

- Always take GABOTON exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- Your doctor will determine what dose is appropriate for you.
- If you have the impression that the effect of GABOTON 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 GABOTON normally except if you have problems with your kidneys.
- Your doctor may prescribe a different dosing schedule and/or dose if

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you have problems with your kidneys.

- Always swallow the capsules whole with plenty of water.
- Continue taking GABOTON until your doctor tells you to stop.

Peripheral Neuropathic Pain:

Take the number of capsules as instructed by your doctor. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased stepwise up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening.

Epilepsy:

Adults and adolescents:

Take the number of capsules as instructed. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased stepwise up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening. The maximum time interval between the doses should not exceed 12 hours to prevent breakthrough convulsions

Children aged 6 years and above:

The dose to be given to your child will be decided by your doctor as it is calculated against your child's weight. The treatment is started with a low initial dose which is gradually increased over a period of approximately 3 days. The usual dose to control epilepsy is 25-35 mg/kg/day. It is usually given in 3 divided doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening. The maximum time interval between the doses should not exceed 12 hours to prevent breakthrough

convulsions

GABOTON is not recommended for use in children below 6 years of age.

When to use it

Gabapentin can be given with or without food.

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

How long to use it

Do not stop taking GABOTON unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week. If you stop taking GABOTON suddenly or before your doctor tells you, there is an increased risk of seizures.

If you forget to use it

It is important to take your medicine every day. However, if you forget to take one or more doses, take another as soon as you remember and then go on as prescribed. Do not take a double dose to replace the forgotten dose.

If you use too much(overdose)

If you take too many capsules, contact your nearest hospital casualty department or tell your doctor immediately.

Symptoms of the overdoses included dizziness, drowsiness, double vision, slurred speech, lethargy and mild diarrhea.

WHILE YOU ARE USING GABOTON?

Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Gaboton.
- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Gaboton to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

GABOTON may produce dizziness, drowsiness and tiredness. You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether this medication affects your ability to perform these activities.

SIDE EFFECTS

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

Very common side-effects which may affect more than 1 person in 10 are listed below:

- Viral infection
- Feeling drowsy, dizziness, lack of coordination
- Feeling tired, fever

Common side-effects which may affect more than 1 person in 100 are listed below:

- Pneumonia, respiratory infection, urinary tract infection, inflammation of the ear
- Low white blood cell counts
- Anorexia, increased appetite
- Anger towards others, confusion, fluctuation in mood, depression, anxiety, nervousness, difficulty with thinking
- Convulsions, jerky movements, difficulty with speaking, loss of memory, tremor, difficulty sleeping, headache, sensitive skin, decreased sensation, difficulty with coordination, unusual

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- eye movement, increased, decreased or absent reflexes
- Blurred vision, double vision
- Vertigo
- High blood pressure, flushing or dilation of blood vessels
- Difficulty breathing, bronchitis, sore throat, cough, dry nose
- Vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhoea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
- Facial swelling, bruises, rash, itch, acne
- Joint pain, muscle pain, back pain, twitching
- Incontinence
- Difficulties with erection
- Swelling in the legs and arms or swelling that may involve the face, trunk and limbs, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
- Decrease in white blood cells, increase in weight
- Accidental injury, fracture, abrasion

Rare side-effects which may affect less than 1 person in 1000 are listed below:

- Decreased platelets (blood clotting cells)
- Allergic reaction such as hives
- Hallucinations
- Problems with abnormal movements such as writhing, jerking movements and stiffness
- Ringing in the ears
- Racing heartbeat
- Inflammation of the pancreas
- Inflammation of the liver, yellowing of the skin and eyes
- Severe skin reactions that require immediate medical attention, swelling of the lips and face, skin rash and redness, hair loss
- Acute kidney failure
- Adverse events following the abrupt discontinuation of gabapentin (anxiety, difficulty

- sleeping, feeling sick, pain, sweating), chest pain
- Blood glucose fluctuations in patients with diabetes, abnormal blood test results suggesting problems with the liver.

Additionally in clinical studies in children, aggressive behaviour and jerky movements were reported commonly.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

STORAGE & DISPOSAL OF GABOTON.

Storage

- Keep out of the reach and sight of children.
- Do not use GABOTON after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month
- Do not store above 30°C.
- Store in the original package

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

Capsule, hard: Yellow coloured hard gelatin capsule containing

white to off-white coloured powder.

Ingredients

Active ingredient

- The active substance is: gabapentin.

GABOTON: Each capsule, hard contains 300 mg of gabapentin.

Inactive ingredients

- The other ingredients in the capsules are:

Capsule contents: Pregelatinised starch, maize starch, talc, colloidal anhydrous silica.

Capsule shell: Yellow iron oxide (E172), titanium dioxide (E171), water, sodium lauryl sulphate, gelatin.

MAL number

MAL09062145A

MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer

Sandoz Private Limited (SPL)
MIDC,
Plot no. 8 A/2 & 8-B
TTC Ind. Area, Kalwe Block
Village Dighe, Navi
Mumbai – 400 708
India

Product Registration Holder

Novartis Corporation (M) Sdn. Bhd.
Level 22, Tower B, Plaza 33,
No.1, Jalan Kemajuan, Seksyen 13,
46200 Petaling Jaya,
Selangor, Malaysia.

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6 April 2015

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