

PATIENT INFORMATION LEAFLET
GABAPENTIN CAPSULES 300mg
(ABLEPT-300)



What is in this leaflet?

- What ABLEPT is used for
- How ABLEPT works
- Before you take ABLEPT
- How to take ABLEPT
- While you are taking ABLEPT
- Side Effects
- Storage and Disposal of ABLEPT
- Product description

What ABLEPT is used for?

Gabapentin belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain.

Epilepsy

Gabapentin is used to treat 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). Your doctor will prescribe Gabapentin for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Gabapentin in addition to your current treatment unless told otherwise. Gabapentin can also be used on its own to treat adults and children over 12 years of age.

Peripheral neuropathic pain

Gabapentin is used to treat long lasting pain caused by damage to the nerves. 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 ABLEPT works

Gabapentin readily enters the brain and prevents seizures in a number of animal models of epilepsy. Gabapentin does not possess affinity for either GABAA or GABAB receptor nor does it alter the metabolism of GABA. It does not bind to other neurotransmitter receptors of the brain and does not interact with sodium channels. Gabapentin binds with high affinity to the $\alpha 2\delta$ (alpha-2-delta) subunit of voltage-gated calcium channels and it is proposed that binding to the $\alpha 2\delta$ subunit may be involved in gabapentin's anti-seizure effects in animals. Broad panel screening does not suggest any other drug target other than $\alpha 2\delta$.

Before you take ABLEPT

Do not take Gabapentin

- if you are allergic to gabapentin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Gabapentin:

- if you suffer from kidney problems
- if you are on haemodialysis (to remove waste products because of kidney failure).

Cases of abuse and dependence have been reported for gabapentin. Talk to your doctor if you have a history of abuse or dependence.

During treatment

If you develop signs such as persistent stomach pain, feeling sick and being sick contact your doctor immediately as these may be signs of acute pancreatitis (an inflamed pancreas).

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

Increase in seizures or new types of seizure have been seen in some people taking gabapentin.

Talk to your doctor or pharmacist if you notice a change to your condition.

If you experience any signs such as feeling dizzy and drowsy (which could increase accidental injury), confusion, loss of consciousness and reduced mental state while taking gabapentin, talk to you doctor or pharmacist for advice.

Important information about potentially serious reactions

A small number of people taking gabapentin get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. You need to know the signs to look out for while you are taking gabapentin.

Read the description of these signs in section 4 of this leaflet under ‘Stop taking this medicine and contact your doctor immediately or go to the nearest hospital casualty department straight away if you experience any of the following signs after taking this medicine as they can be serious’

Other medicines and Gabapentin

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

Medicines containing opioids such as morphine

If you are taking any medicines containing opioids (such as morphine), please tell your doctor or pharmacist as opioids may increase the effect of gabapentin. In addition, combination of gabapentin with opioids may cause symptoms like sleepiness and/or decrease in breathing.

Gabapentin is not expected to interact with other antiepileptic medicines or oral contraceptive pills containing norethindrone or ethinyl estradiol.

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

Antacids for indigestion

If gabapentin and antacids containing aluminium and magnesium are taken at the same time, absorption of gabapentin from the stomach may be reduced. It is therefore recommended that

Gabapentin is taken at least two hours after taking an antacid.

Pregnancy and breast-feeding

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.

Pregnancy

Gabapentin 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 stop taking this medicine as this may lead to breakthrough seizure, which could have serious consequences for you and your baby.

Breast-feeding

Gabapentin, passes into human milk. Because the effect on the nursing new-born is unknown, it is not recommended to breast-feed your baby while taking Gabapentin.

Driving and using machines

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

Gabapentin contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

How to take ABLEPT

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. If you have the impression that the effect of Gabapentin is too strong or too weak, talk to your doctor or pharmacist. Always swallow the capsules whole with plenty of water. This medicine may be taken with or without food. Continue taking Gabapentin until your doctor tells you to stop.

Epilepsy:***Use in 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.

Use in 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 recommended 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.

While you are taking ABLEPT

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

Peripheral Neuropathic Pain:

Take the number of capsules as instructed by your doctor. Your doctor will usually build up your dose gradually. The recommended 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.

Older patients

If you are an elderly patient (over 65 years of age), you should take Gabapentin normally except you have problems with your kidneys.

Patients with kidney problems or are receiving haemodialysis

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys or are undergoing haemodialysis.

If you take more Gabapentin than you should

If you or someone else accidentally takes too many capsules, or if you think a child has swallowed any, contact your doctor or go to the nearest hospital emergency unit **immediately**. Take along any capsules that are left, the container and the label so that the hospital can easily tell what medicine you have taken.

As this medicine may make you drowsy, it is recommended that you ask someone else to drive you to the doctor or hospital, or that you call an ambulance. Signs of an overdose include dizziness, double vision, slurred speech, loss of consciousness, drowsiness and mild diarrhoea.

If you forget to take Gabapentin

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Gabapentin

Do not stop taking Gabapentin 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 gabapentin suddenly or before your doctor tells you, there

is an increased risk of seizures. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Stop taking this medicine and contact your doctor immediately or go to the nearest hospital casualty department straight away if you experience any of the following signs after taking this medicine as they can be serious:

Common (may affect up to 1 in 10 people)

- Serious chest infection which may cause fever, chills, shortness of breath, cough, phlegm and occasionally blood (pneumonia)
- Fits (convulsions)
- Decreased white blood cell count (leucopenia) which may cause you to suffer from more frequent infections e.g. sore throat, fever, severe chills and mouth ulcers etc.

Rare (may affect up to 1 in 1,000 people)

- Loss of consciousness
- **Not known** (frequency cannot be estimated from the available data)
- Anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)
- Severe skin reactions that require immediate attention such as swelling of the lips and face, skin rash and redness (these may be signs of a serious allergic reaction).
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome) appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). The rash may progress to widespread blistering or peeling of the skin.
- A severe condition of the skin (Erythema multiforme) that may affect the mouth and other parts of the body signs include red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centered marks. Those affected may have fever, sore throat, headache and/or diarrhoea.
- An inflamed pancreas which may cause stomach pain (spreading to the back) and being sick.
- Kidney disease leading to passing less urine than usual, feeling or being sick, or confused (acute kidney failure).
- destruction of muscle fibres associated with muscle cramps, muscle pain, fever and red-brown discoloration of the urine (rhabdomyolysis)

Gabapentin may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have rash when you get this type of reaction. It may cause you to be hospitalized or to stop Gabapentin.

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 signs may be the first signs of a serious reaction. A doctor should examine you to decide if you should continue taking Gabapentin.

Other possible side effects:

Very common (may affect more than 1 in 10 people)

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

Common (may affect up to 1 in 10 people)

- Urinary tract infection, general infections, inflammation of the ear
- Loss of appetite or an increased appetite.
- Anger towards others, confusion, fluctuation in mood, depression, anxiety, nervousness, difficulty with thinking.
- Jerky movements, difficulty with speaking, loss of memory, shaking, difficulty sleeping, headache, numbness, tingling or pins and needles, decreased sensation, difficulty with coordination
- Rapid unusual eye movement, increased, decreased or absent reflexes.
- Blurred vision, double vision.
- Spinning sensation (vertigo).
- High blood pressure, flushing or dilation of blood vessels. Shortness of breath, chest infection (bronchitis), sore throat and discomfort when swallowing, cough, runny or blocked nose.
- vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhoea, stomach pain, indigestion, constipation, dry mouth or throat, wind.
- Facial swelling, bruises, acne.
- Joint pain, muscle pain, back pain, twitching.
- Difficulty getting or maintaining an erection.
- Swelling in the legs and arms difficulty with walking, pain, generally feeling unwell, flu-like symptoms.
- Increase in weight.
- Accidental injuries, such as broken bones, scratches or bruises.

Uncommon (may affect up to 1 in 100 people)

- Racing heartbeat
- Unusually reduced or slow body movement
- Swelling that may involve the trunk
- Increase in liver enzymes and bilirubin seen in a blood test
- Fall
- Difficulty with thinking
- High blood sugar (most often seen in patients with diabetes)
- Nettle rash or itchy rash
- Agitation (a state of chronic restlessness and unintentional and purposeless motions)

Rare (may affect up to 1 in 1,000 people)

- Low blood sugar (most often seen in patients with diabetes)
- Loss of consciousness

Not known (frequency cannot be estimated from the available data)

- Sensing things that are not real (hallucinations)
- Ringing in the ears
- Problems with abnormal movements such as writhing, jerking movements and stiffness affecting the eyes, head, neck and body
- Hair loss

- Uncontrolled passing of urine
- Increased breast tissue, breast enlargement in males
- Problems with sexual functioning including changes in sex drive, inability to reach a sexual climax, delayed ejaculation
- Signs of withdrawal (such as anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
- Increase in creatine phosphokinase seen in a blood test
- Low levels of sodium in the blood

Additional side effects in children

Aggressive behaviour was commonly reported.

Storage and Disposal of ABLEPT

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the label, carton or bottle after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description***What it looks like***

Dark red / Dark red '1' size capsule shells containing free flowing white powder.

Each hard gelatin capsule contains:

Gabapentin USP 300 mg

Ingredients

The active substance is Gabapentin.

The other ingredients are Maize starch, Talc and HG Cap 1 DR red / DR red plain.

Manufacturer

MICRO LABS LIMITED

92, SPICOT

HOSUR - 635126

INDIA.

Marketing Authorization Holder

MICRO LABS LIMITED

#27, Race Course Road,

Bangalore – 560001

INDIA

Date of Revision:

Feb 2018