

Patient Information Leaflet for EPLEPTIN[®] capsules

SCHEDULING STATUS

S3

EPLEPTIN[®] 100 mg capsules

EPLEPTIN[®] 300 mg capsules

EPLEPTIN[®] 400 mg capsules

Sugar free


Read all of this leaflet carefully before you start taking EPLEPTIN[®]

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- EPLEPTIN[®] has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What EPLEPTIN[®] is and what it is used for
2. What you need to know before you take EPLEPTIN[®]
3. How to take EPLEPTIN[®]
4. Possible side effects
5. How to store EPLEPTIN[®]

1. What EPLEPTIN[®] is and what it is used for

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EPLEPTIN[®] contains the active substance gabapentin. This medicine is used to treat various forms of epilepsy (a central nervous system (neurological) disorder in which brain activity becomes abnormal), also called fits.

Your doctor will prescribe EPLEPTIN[®] for you to help treat your epilepsy when your current treatment is not fully controlling your condition or where your current treatment is causing problems such as side effects. You should only take EPLEPTIN[®] in addition to your current treatment unless told otherwise.

2. What you need to know before you take EPLEPTIN[®]

Do not take EPLEPTIN[®] if you:

- If you are hypersensitive (allergic) to gabapentin or to any of the other ingredients of EPLEPTIN[®] (listed in section 6).
- If you are under the age of 12 years.
- If you are pregnant or breastfeeding your infant (see pregnancy and breastfeeding).
- If you have kidney problems.

Warnings and precautions

- If you are allergic to any of the ingredients of EPLEPTIN[®] (see section 6).
- If you realise that you are becoming depressed or if any existing depression worsens.
- If you have any suicidal thoughts or behaviour, or if your mood or behaviour changes, or if you have a radical change in personality. A small number of people being treated with anti-epileptics such as EPLEPTIN[®] have had thoughts of harming or killing themselves. If at any time you have these thoughts, contact your doctor immediately.
- If you have a history of medicine or drug abuse and dependence, talk to your doctor before taking EPLEPTIN[®] as EPLEPTIN[®] can cause drug dependence.
- If you suffer from any renal disease. Be sure to inform your doctor before taking EPLEPTIN[®].
- If you need to stop EPLEPTIN[®] suddenly or reduce your dose, your doctor should monitor you carefully. Withdrawal symptoms may occur shortly after stopping EPLEPTIN[®]. Symptoms that may

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occur after stopping EPLEPTIN® include anxiety, insomnia, nausea, pains, sweating, tremor, headache, depression, feeling abnormal, dizziness, and malaise.

- EPLEPTIN® should not be used if you have mixed seizures, and is not considered effective against absences seizures. If seizures get more frequent while using EPLEPTIN® consult your doctor immediately.
- If they have to perform an analysis of proteins in your urine, warn them that you are taking EPLEPTIN® as some tests (Ames N Multistick G reactive strip test) are sensitive and can artificially alter the results (see **Other medicines with EPLEPTIN®**).
- If you have a history of developing a serious skin reaction (for e.g. severe cutaneous adverse reactions, Stevens-Johnson syndrome, toxic epidermal necrolysis or drug rash with eosinophilia and systemic symptoms) with the use of EPLEPTIN®, treatment must not be restarted.

Children and adolescents

EPLEPTIN® should not be given to children below 12 years of age.

Other medicines with EPLEPTIN®:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Certain medicines can interact with EPLEPTIN®. In these cases it may be necessary to change the dose or interrupt the treatment with one of the medicines.

It is especially important that you inform your doctor if you are taking any of the following medicines:

Antacids that contain aluminium or magnesium, as EPLEPTIN® must be administered two hours afterwards.

EPLEPTIN® can be used with other antiepileptics such as phenytoin, carbamazepine, valproic acid, phenobarbital, etc.

It is also possible to combine its use with the administration of contraceptive (birth control) medicines that contain noretindrone and/or ethinyl oestradiol.

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Concurrent use of EPLEPTIN® with alcohol and other central nervous system (CNS) depressants (such as tranquilisers) may increase the CNS depressant effects e.g. decrease in alertness and increase in sleepiness.

You should not take EPLEPTIN® with any CNS (central nervous system) depressants, including opioids if you are a frail patient, elderly or you have serious underlying respiratory disease as it may lead to respiratory depression, sedation, and death.

It is important to tell your healthcare professional if you are taking any medication containing morphine as it may cause CNS (central nervous system) depression and patients need to be monitored closely.

False positive tests showing protein in your urine may occur with AMES Multistix-SG (see warnings and precautions).

Taking EPLEPTIN® with food and drink:

EPLEPTIN® can be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy:

Do not take EPLEPTIN® if you are pregnant as it may harm your unborn baby.

Breastfeeding:

Do not take EPLEPTIN® while you are breastfeeding.

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EPLEPTIN® crosses the placenta. Withdrawal syndrome has been reported in newborns exposed to EPLEPTIN® during pregnancy. Newborns should be monitored carefully.

Driving and using machinery:

EPLEPTIN® can frequently cause dizziness, tiredness, vertigo or other related symptoms. If you feel any of these symptoms, refrain from driving a vehicle, using machinery or performing any activity that requires concentration, until you know whether EPLEPTIN® affects your ability to perform these activities.

3. How to take EPLEPTIN®

Do not share medicines prescribed for you with any other person.


Always take EPLEPTIN® exactly as your doctor or pharmacist has instructed you.

You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of EPLEPTIN® is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you how long your treatment will last as well as the dose to start with and how to increase it. Take EPLEPTIN® with a sufficient quantity of liquid (a glass of water).

The usual dose for adults and children over 12 years is 300 mg EPLEPTIN® three times a day.

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Dosages of 900 mg to 1 800 mg per day, taken in three divided doses are effective for most patients.

EPLEPTIN® can be taken with or without food. Always swallow the capsules with plenty of water.

EPLEPTIN® is not recommended in children under 12 years.

Elderly patients or patients with kidney problems or on dialysis treatment have to follow the instructions of their doctor.

If you take more EPLEPTIN® than you should:

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre.


If you take too much EPLEPTIN® you may experience one or more of the following symptoms: dizziness, double vision, difficulty in speaking, sleeplessness, sleepiness and mild diarrhoea.

If you forget to take EPLEPTIN®:

If you forgot to take your dose, take it as soon as you remember, as long as less than four hours passed since the regularly scheduled time. If it has been more than four hours, take the subsequent dose. Do not allow more than 12 hours to pass without taking EPLEPTIN®. If this occurs immediately inform your doctor.

If you stop taking EPLEPTIN®:

Do not stop taking EPLEPTIN® or change the dose without consulting your doctor beforehand. Never suspend treatment brusquely, because an acute attack could be provoked (epileptic state).

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If your treatment is stopped it should be done gradually over a minimum of 1 week. If you stop taking EPLEPTIN® suddenly or before your doctor tells you may have one or more of the following symptoms: anxiety, inability to fall asleep, nausea, and sweating, sudden unexplained deaths, depression, headache, pain, tremor (shaking), agitation, panic attacks, diarrhoea, dizziness, increased heart rate, confusion and swelling that may involve the face, trunk and limbs.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible Side Effects

EPLEPTIN® can have side effects.

Not all side effects reported for EPLEPTIN® are included in this leaflet. Should your general health worsen or you experience any untoward effect while taking EPLEPTIN®, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking EPLEPTIN® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing
- Anaphylactic reaction, a life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. Symptoms may include 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, frequent infections increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia)
- Erythema multiforme (severe condition of the skin that may affect the mouth and other parts of the body. Symptoms 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

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form raised, red, pale-centred marks. Those affected may have fever, sore throat, headache and/or diarrhoea)

- Stevens-Johnson syndrome (severe blistering or peeling of the skin; bleeding in the lips, eyes, mouth, nose and genitals; swelling around the eyes, lips and face, rashes caused by exposure to sunlight)
- A rash or itching
- Fainting
- Yellowing of your skin and eyes, also called jaundice
- Patients and caregivers should seek medical attention immediately if someone experiences symptoms of respiratory problems, because these can be life-threatening. Symptoms to watch for include:
 - Confusion or disorientation
 - Unusual dizziness or light-headedness
 - Extreme sleepiness or lethargy
 - Unresponsiveness, which means a person does not answer or react normally or you cannot wake up them up
 - Bluish-coloured or tinted skin, especially on the lips, fingers, and toes

These are all very serious side effects. If you have them you may have had a serious allergic reaction to EPLEPTIN®. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Acute anxiety, hallucinations, sleeplessness or over excitement
- Decrease in white blood cells (signs of recurrent infections or fever)
- Reduced numbers of blood platelets. Symptoms may include bleeding or bruising more easily than normal (thrombocytopenia)

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- Fast or irregular heartbeats, chest pain, faster heart beat
- Inflammation of pancreas. Symptoms may include severe upper stomach pain, often with nausea and vomiting
- Thoughts about killing or harming yourself
- Inflammation of liver, symptoms may include nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine
- Decreased urinary output, swelling due to fluid retention, nausea, fatigue and shortness of breath
- A rash combined with systemic symptoms such as fever, night sweats, fatigue, cough, chest pain, swelling, weakness, confusion and coma

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects:

- Tiredness, sleepiness, dizziness, difficulty controlling your muscles, trembling
- Viral infection, respiratory infection, pneumonia (serious lung infection. Symptoms may include fever, chills, shortness of breath, cough, phlegm and occasionally blood), urinary tract infection (symptoms may include strong, persistent urge to urinate, burning sensation when urinating, passing frequent, small amounts of urine, strong-smelling urine); inflammation of the ear or other infections
- Vertigo (dizziness or spinning feeling in your head)
- Double vision, lazy eye, involuntary eye movement
- Depression, frequent mood changes
- Muscle pain
- Swelling of the limbs due to water retention
- Increased appetite, loss of appetite

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- Confusion, depression, emotional lability, nervousness, thinking abnormal, hostility, anxiety
- Difficulty in controlling movements, dizziness, sleepiness, loss of memory, coordination abnormal, difficulty in speaking, inability to fall asleep, headache, nystagmus (rapid, uncontrollable movements of the eyes), tremor (shaking), fits, hyperkinesias (disorder of children marked by hyperactivity and inability to concentrate), sensations such as paresthesia (tingling or pricking, "pins-and-needles" sensation), diminished capacity for physical sensation, especially of the skin, coordination abnormal, increased, decreased, or absent reflexes
- Amblyopia (lazy eye, reduced vision in one eye caused by abnormal visual development early in life), double vision
- Vertigo (spinning sensation)
- Widening of blood vessels, hypertension (high blood pressure. Symptoms may include severe headaches, nosebleed, fatigue or confusion, vision problems, chest pain, difficulty breathing, irregular heartbeat)
- Coughing, pharyngitis (sore throat and discomfort when swallowing), rhinitis (runny or blocked nose, sneezing, facial pressure or pain), dyspnoea (shortness of breath), bronchitis (inflammation of the lining of bronchial tubes, which carry air to and from the lungs. Symptoms may include cough, fatigue or generally feeling unwell, runny nose or post-nasal drip, chest pressure, headache, shortness of breath, sleeping difficulty, or sore throat)
- Abdominal pain, constipation, dental abnormalities, diarrhoea (loose stools), indigestion, mouth or throat dry, nausea and/or vomiting, gingivitis (common and mild form of gum disease that causes irritation, redness and swelling of your gingiva, the part of your gum around the base of your teeth), flatulence (excessive gas in the stomach or bowel)
- Acne, itching, rash, swelling of face, bruises
- Back pain, muscle pain, twitching, joint pain
- Impotence (difficulties with erection)
- Tiredness, fever, swelling of hands, ankles or feet, difficulty with walking, unusual weakness, pain, generally feeling unwell, flu-like symptoms (fever or feeling feverish/having chills, cough, shortness

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of breath or difficulty breathing, tiredness, sore throat, runny or stuffy nose, muscle pain or body aches, headache)

- Weight gain
- Abrasion, fracture, accidental injury

Less frequent:

- Headache, difficulty pronouncing words, memory loss, confusion, trouble falling asleep, twitching, sensation of tingling, nervousness
- Abnormal coordination
- Nausea and vomiting, heartburn, discomfort in the stomach, dryness of mouth or throat, constipation, diarrhoea, dental problems
- Runny nose, sore throat, coughing, chest infection
- Acne, small, flat red spots on skin
- Toxic epidermal necrolysis (extensive exfoliation of the outer layer of skin and inner layer of nose and mouth)
- Abnormal thinking
- Erection problems
- Back pain, fracture
- Widening of blood vessels
- Red or purple discolouration on the skin
- Viral infection
- Increased appetite, resulting in weight gain
- Fever
- Hyperglycaemia (increase in blood glucose levels. Symptoms may include increased thirst and/or hunger, blurred vision, frequent urination (peeing), headache)
- Hypoglycaemia (decrease in blood glucose levels. Symptoms may include an irregular or fast heartbeat, tiredness, pale skin, shakiness, anxiety, sweating, hunger, irritability)

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- Agitation (state of anxiety or nervous excitement)
- Unusually reduced or slow body movement, mental impairment, loss of consciousness
- Respiratory depression (breathing disorder characterized by slow and ineffective breathing)
- Difficulty in swallowing
- Generalized oedema (swelling that may involve the face, trunk and limbs)
- Hyponatraemia (low sodium levels in the blood. Symptoms may include Muscle cramps or weakness, nausea and vomiting, lethargy, or low energy, headache and confusion, mental status changes, fits)
- Hallucinations (seeing, feeling or hearing things that are not there)
- Involuntary fidgeting and movement, dyskinesia (uncontrollable twitching, jerking or writhing movements), and dystonia (uncontrollable muscle spasms affecting the eyes, head, neck and body), spastic torticollis (disorder where the muscles of the neck contract uncontrollably, making the head turn into various postures) and myoclonus (sudden, involuntary muscle jerk, shake or spasm)
- Tinnitus (ringing sensation in the ears)
- Jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems)
- Alopecia (hair loss)
- Urinary incontinence (loss of bladder control, varying from a slight loss of urine after sneezing, coughing or laughing, to complete inability to control urination)
- Breast hypertrophy (condition in which breasts grow so heavy that they cause problems), gynaecomastia (breast enlargement in men), sexual dysfunction (including changes in sex drive, delayed ejaculation and inability to achieve a sexual climax)
- Change in blood test results
- Myoclonus (infrequent muscle twitches, low magnesium or muscle fatigue)

If you are an elderly patient, you may be more sensitive to these adverse reactions.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your healthcare professional. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of EPLEPTIN®.

5. How to store EPLEPTIN®

- Store at or below 25 °C.
- Protect from light and moisture.
- Keep bottle tightly closed until required for use.
- **STORE ALL MEDICINE OUT OF THE REACH OF CHILDREN.**
- Do not use the capsules after the expiry date shown on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EPLEPTIN® contains

The active substance is gabapentin.

Each capsules contains gabapentin 100, 300 and 400 mg.

The other ingredients are: Calcium sulfate dihydrate, pregelatinised starch, calcium carbonate, glyceryl behenate.


Composition of capsule: EPLEPTIN® 100 mg:

Gelatin, water, sodium lauryl sulphate, titanium dioxide.

Composition of capsule: EPLEPTIN® 300 mg:

Gelatin, water, sodium lauryl sulphate, titanium dioxide, iron oxide yellow.

Composition of capsule: EPLEPTIN® 400 mg:

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Gelatin, water, sodium lauryl sulphate, titanium dioxide, iron oxide yellow, iron oxide red.

What EPLEPTIN® looks like and contents of the pack

EPLEPTIN® 100 mg: Hard gelatine size '3' capsules, white cap and white body with "137" imprinted in black on cap and body, containing white crystalline powder.

EPLEPTIN® 300 mg: Hard gelatine size '1' capsules, yellow cap and yellow body with "138" imprinted in black on cap and body, containing white crystalline powder.

EPLEPTIN® 400 mg: Hard gelatine size '0' capsules, orange cap and orange body with "139" imprinted in black on cap and body, containing white crystalline powder.

EPLEPTIN® 100 mg is packed into 75 cc white round plastic bottles with 33 mm plastic white ribbed caps. 100 Capsules per bottle.

EPLEPTIN® 300 mg is packed into 150 cc white round plastic bottles with 38 mm plastic white ribbed caps. 100 Capsules per bottle.

EPLEPTIN® 400 mg is packed into 150 cc white round plastic bottles with 38 mm plastic white ribbed caps. 100 Capsules per bottle.

Blister Pack 100's: 10 blisters of 10 Capsules each packed in the silver Aluminium/clear PVC/PVDC blister. Ten blisters of ten Capsules each are packed in an outer carton.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd.

14 Lautre Road,

Stormill, Ext. 1, Roodepoort

Johannesburg 1724

011 495 0100

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Registration Numbers

EPLEPTIN® 100 mg (capsules): A40/2.5/0158

EPLEPTIN® 300 mg (capsules): A40/2.5/0159

EPLEPTIN® 400 mg (capsules): A40/2.5/0160

Namibia

Scheduling:

NS2

EPLEPTIN® 100 mg capsules: 07/2.5/0090

EPLEPTIN® 300 mg capsules: 07/2.5/0089

EPLEPTIN® 400 mg capsules: 07/2.5/0088

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