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

Signed:

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

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 **O**ther 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.

Signed:

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.

Signed:

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 overdosage, 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).

Signed:

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

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 wakeup 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)

Signed:

- 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

Signed:

- 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

Signed:

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)

Signed:

- 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.

Signed:

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:

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

Signed:

This leaflet was last revised in

Date of registration: 6 October 2006

Date or revision of text: 09 September 2024

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

Signed:

Pasiëntinligtingsblad vir EPLEPTIN® kapsules

SKEDULERINGSTATUS

S3

EPLEPTIN® 100 mg kapsules

EPLEPTIN® 300 mg kapsules

EPLEPTIN® 400 mg kapsules

Suikervry

Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om EPLEPTIN® te neem.

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer as jy verdere vrae het.
- EPLEPTIN® is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk

1. Wat EPLEPTIN® is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy EPLEPTIN® gebruik
3. Hoe om EPLEPTIN® te gebruik
4. Moontlike newe-effekte
5. Hoe om EPLEPTIN® te bewaar

1. Wat EPLEPTIN® is en waarvoor dit gebruik word

EPLEPTIN® bevat die aktiewe bestanddeel gabapentien. Hierdie medisyne word gebruik om verskillende vorme van epilepsie te behandel ('n sentrale senuweestelsel- (neurologiese) versteuring waarin die breinaktiwiteit abnormaal raak), ook toevalle genoem.

Jou dokter sal EPLEPTIN® vir jou voorskryf om jou epilepsie te help behandel wanneer jou huidige behandeling jou toestand nie ten volle beheer nie of wanneer jou huidige behandeling probleme, soos newe-effekte, veroorsaak. Jy moet EPLEPTIN® slegs bykomend tot jou huidige behandeling neem, tensy jy andersins ingelig is.

2. Wat jy behoort te weet voordat jy EPLEPTIN® neem

Moenie EPLEPTIN® neem nie:

- As jy hipersensitief (allergies) is vir gabapentien of vir enige van die ander bestanddele van EPLEPTIN® (gelys in Afdeling 6).
- As jy onder die ouderdom van 12 jaar is.
- As jy swanger is of jou baba borsvoed (sien **Swangerskap en borsvoeding**).
- As jy nierprobleme het.

Waarskuwings en voorsorgmaatreëls

- As jy allergies is vir enige van die bestanddele van EPLEPTIN® (sien Afdeling 6)
- As jy besef dat jy depressief raak of as enige bestaande depressie vererger.
- As jy enige selfdoodgedagtes of gedrag het, of as jou gemoed of gedrag verander, of as jy 'n radikale verandering in persoonlikheid ondergaan. 'n Klein aantal persone wat met anti-epileptiese middels soos EPLEPTIN® behandel is, het gedagtes gehad om hulleself seer of selfs dood te maak. As jy op enige stadium sulke gedagtes het, moet jy jou dokter dadelik laat weet.

- As jy ‘n geskiedenis het om medisyne of dwelms te misbruik of afhanklik is daarvan, moet jy met jou dokter praat voordat jy EPLEPTIN® neem, aangesien EPLEPTIN® geneesmiddelafhanklikheid kan veroorsaak.
- As jy aan enige niersiekte ly. Maak seker dat jy jou dokter inlig voordat jy EPLEPTIN® neem.
- As jy EPLEPTIN® skielik moet staak of jou dosis verlaag, moet jou dokter jou noukeurig monitor. Onttrekingsimptome kan kort nadat EPLEPTIN® gestaak is, voorkom. Simptome wat mag voorkom nadat EPLEPTIN® gestaak is, sluit angstigheid, slapeloosheid, naarheid, pyn, sweet, bewerigheid, hoofpyn, depressie, abnormale gevoel, duiseligheid en algemene gevoel van ongesteldheid in.
- EPLEPTIN® moet nie gebruik word vir gemengde toevalle nie, aangesien dit nie beskou word as doeltreffend teen afwesigheidstoevalle nie. Indien toevalle meer dikwels voorkom terwyl EPLEPTIN® gebruik word, moet jou dokter onmiddellik ingelig word.
- As hulle ‘n analise van proteïene in jou urine moet uitvoer, moet jy hulle waarsku dat jy EPLEPTIN® neem, aangesien sommige toetse (Ames N Multistick G reaktiewe toetsstrokie) sensitief is en kan die resultate kunsmatig verander (sien **Ander medisyne saam met EPLEPTIN®)**.
- As jy ‘n geskiedenis het om ernstige velreaksies te ontwikkel (byvoorbeeld ernstige ongewenste velreaksies, Stevens-Johnson se sindroom, toksiese epidermale nekrolise of geneesmiddeluitslag met eosinofilie en sistemiese simptome) met die gebruik van EPLEPTIN®, moet behandeling nie weer hervat word nie.

Kinders en adolessente

EPLEPTIN® moet nie aan kinders onder 12-jarige ouderdom toegedien word nie.

Ander medisyne saam met EPLEPTIN® :

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Lig jou professionele gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik (dit sluit aanvullende of tradisionele medisyne in).
Sekere medisyne kan met EPLEPTIN® wisselwerk. In hierdie gevalle kan dit nodig wees om die dosis te verander of die behandeling te onderbreek met een van hierdie middels.
Dit is veral belangrik dat jy jou dokter inlig as jy enige van die volgende medisyne neem:
Teensuurmiddels wat aluminium of magnesium bevat, aangesien EPLEPTIN® ten minste twee uur daarná toegedien moet word.

EPLEPTIN® kan saam met ander anti-epileptiese middels soos fenitoïen, karbamasepien, valproësuur, fenobarbitoon, ens. toegedien word.
Dit is ook moontlik om die gebruik te kombineer met die toediening van voorbehoedmiddels (geboortebeperkingsmedisyne) wat noretindroon en/of etinielestradiol bevat.

Gesamentlike gebruik van EPLEPTIN® met alkohol en ander sentrale senuweestelsel (SSS) depressante (soos kalmeermiddels) kan die effekte van die SSS-depressant verhoog bv. afname in waaksaamheid en toename in slaperigheid.

Jy moenie EPLEPTIN® saam met enige SSS (sentrale senuweestelsel) onderdrukkers neem nie, insluitend opioïede, indien jy ‘n verswakte pasiënt is, ‘n bejaarde is of as jy ernstige onderliggende respiratoriese siekte het, aangesien dit kan lei tot respiratoriese onderdrukking, sedasie en die dood.
Dit is belangrik om jou gesondheidsorgverskaffer in te lig as jy enige medisyne wat morfien bevat gebruik, aangesien dit SSS (sentrale senuweestelsel) onderdrukking kan veroorsaak en pasiënte moet noukeurig gemonitor word.

Signed:

Vals positiewe toetse wat proteïene in jou urine toon, kan voorkom met AMES Multistix-SG (sien **Waarkuwings en voorsorgmaatreëls**).

Neem van EPLEPTIN® saam met voedsel en drinkgoed:

EPLEPTIN® kan met of sonder voedsel geneem word.

Swangerskap en borsvoeding:

As jy swanger is of borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, moet jy eers jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat jy hierdie medisyne gebruik.

Swangerskap:

Moenie EPLEPTIN® gebruik as jy swanger is nie, aangesien dit skadelik mag wees vir jou ongebore baba.

Borsvoeding:

Moenie EPLEPTIN® gebruik terwyl jy borsvoed nie.

EPLEPTIN® steek die plasenta oor. Onttrekkingsimptome is aangemeld by pasgeborenes wat blootgestel is aan EPLEPTIN® tydens swangerskap. Pasgeborenes moet noukeurig gemonitor word.

Bestuur en gebruik van masjinerie:

EPLEPTIN® kan dikwels duiseligheid, moegheid, vertigo of ander verwante simptome veroorsaak. Indien jy enige van hierdie simptome ervaar, weerhou jou daarvan om ‘n voertuig te bestuur of masjinerie te gebruik of enige aktiwiteit uit te voer wat konsentrasie vereis totdat jy weet of EPLEPTIN® jou vermoë om hierdie aktiwiteite uit te voer, affekteer.

Signed:

3. Hoe om EPLEPTIN® te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem EPLEPTIN® altyd presies soos wat dit deur jou dokter of apteker aan jou voorgeskryf is.

Jy moet met jou dokter of apteker bevestig as jy onseker is.

Praat met jou dokter of apteker as jy onder die indruk is dat die effek van EPLEPTIN® te sterk of te swak vir jou is.

Jou dokter sal jou inlig oor hoe lank jou behandeling sal voortduur asook die dosis om mee te begin en hoe dit verhoog moet word. Neem EPLEPTIN® met ‘n genoegsame hoeveelheid vloeistof (‘n glas water).

Die normale dosis vir volwassenes en kinders bo 12-jarige ouderdom is 300 mg EPLEPTIN® drie keer per dag. Dosisse van 900 mg tot 1 800 mg per dag, in drie verdeelde dosisse geneem, is effektief by die meeste pasiënte.

EPLEPTIN® kan met of sonder voedsel geneem word. Sluk die kapsules altyd met genoegsame water in.

EPLEPTIN® word nie aanbeveel by kinders onder 12-jarige ouderdom nie.

Bejaarde pasiënte of pasiënte met nierprobleme of op dialisebehandeling moet die instruksies van hulle dokter volg.

As jy meer EPLEPTIN® geneem het as wat jy behoort te neem:

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak jou naaste hospitaal of gifbeheersentrum.

As jy te veel EPLEPTIN® geneem het, kan jy een of meer van die volgende simptome ervaar: duiseligheid, dubbelvisie, spraakprobleme, slapeloosheid, slaperigheid, en ligte diarree.

As jy vergeet het om EPLEPTIN® te neem:

As jy vergeet het om jou dosis te neem, neem dit so gou as wat jy onthou, solank minder as vier uur verloop het sedert die normale geskeduleerde tyd. As dit meer as vier uur is, neem die volgende dosis. Moenie toelaat dat meer as 12 uur verbygaan sonder om EPLEPTIN® te neem nie. Indien dit gebeur, moet jy jou dokter inlig.

As jy ophou om EPLEPTIN® te neem:

Moenie ophou om EPLEPTIN® te neem of die dosis te verander sonder om jou dokter vooraf te raadpleeg nie. Moenie behandeling skielik staak nie, omdat ‘n akute aanval uitgelok kan word (epileptiese toestand).

As jou behandeling gestaak word, moet dit geleidelik oor ‘n minimum tydperk van 1 week gedoen word. As jy skielik ophou om EPLEPTIN® te neem of voordat jou dokter jou aangesê het, kan jy een of meer van die volgende simptome ervaar: angstigheid, onvermoë om aan die slaap te raak, naarheid, sweet, skielike onverklaarbare sterftes, depressie, hoofpyn, pyn, bewerigheid (rukkings), agitasie, paniekaanvalle, diarree, duiseligheid, verhoogde hartritme, verwarring en swelling wat die gesig, romp en ledemate kan betrek.

Vra jou dokter of apteker as jy enige verder vrae oor die gebruik van hierdie produk het.

4. Moontlike Newe-Effekte

EPLEPTIN® kan newe-effekte hê.

Nie alle newe-effekte wat vir EPLEPTIN® aangemeld is, is in hierdie inligtingsblad ingesluit nie. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies indien jou algemene gesondheid verswak of as jy enige ongewenste effekte ervaar terwyl jy EPLEPTIN® neem.

Staak die gebruik van EPLEPTIN® en lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as enige van die volgende gebeur:

- Swelling van jou hande, voete, enkels, gesig, lippe, mond, of keel wat dit moeilik maak om te sluk of asem te haal
- Anafilaktiese reaksie, ‘n lewensbedreigende allergiese reaksie wat jou vel of ander dele van jou liggaam soos jou lewer of bloedselle kan affekteer. Simptome kan uitslag, galbulte, koors, geswelde kliere wat nie verdwyn nie, swelling van jou lippe en tong, vergeling van jou vel of die wit van jou oë, dikwelse infeksie met verhoogde vlakke van lewerensieme wat waargeneem word in bloedtoetse en ‘n verhoging in ‘n tipe witbloedsel (eosinofilie) insluit;
- Veelvuldige eriteem (‘n ernstige toestand van die vel wat die mond en ander dele van die liggaam kan affekteer). Simptome sluit in: rooi, dikwels jeukerige kolletjies, soortgelyk aan die uitslag van masels, wat op die ledemate begin en somtyds op die gesig en die res van die liggaam. Die kolletjies kan blasies vorm en mag ontwikkel om opgehewe, rooi merke te vorm wat bleek in die middel is. Die wat geaffekteer is, kan koors, seerkeel, hoofpyn en/of diarree hê);
- Stevens-Johnson se sindroom (ernstige blasievorming of afskilfering van die vel; bloeding van die lippe, oë, mond, neus en geslagsdele; swelling rondom die oë, lippe en gesig, uitslag veroorsaak deur blootstelling aan sonlig)
- ‘n Uitslag of gejeuk
- Floute
- Vergeling van die vel en oë, ook bekend as geelsug.
- Pasiënte en versorgers moet onmiddellik mediese hulp inroep indien iemand simptome van respiratoriese probleme ondervind omdat hierdie lewensbedreigend kan wees.

  Simptome om waargeneem te word, sluit in:
- Verwarring of disoriëntasie
- Ongewone duiseligheid of lighoofdigheid

Signed:

- Uitermatige slaperigheid of traagheid
- Terughoudendheid, wat beteken dat ‘n persoon nie antwoord of normaal reageer of jy kan hulle nie wakker kry nie
- Blouerige-gekleurde of getinte vel, veral op die lippe, vingers en tone

Hierdie is almal baie ernstige newe-effekte. As jy hulle het, kon jy ‘n ernstige allergiese reaksie teenoor EPLEPTIN® gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Akute angstigheid, hallusinasies, slapeloosheid of oor-opgewondenheid.
- Afname in witbloedselle (tekens van hehaaldelike infeksie of koors)
- Afname in getal bloedplaatjies. Simptome kan bloeding of makliker kneusing as normaalweg (trombositopenie) insluit
- Vinnige of onreëlmatige hartklop, borspyn, vinniger hartklop;
- Inflammasie van die pankreas. Simptome kan erge maagpyn in die boonste gedeelte van die maag, dikwels met naarheid en braking, insluit
- Gedagtes om jouself dood te maak of te beseer
- Ontsteking van die lewer, simptome kan naarheid, braking, eetlusverlies, algemene siekerige gevoel, koors, gejeuk, vergeling van die vel en oë, ligte gekleurde stoelgang, donker gekleurde urine insluit
- Verlaagde urienproduksie, swelling as gevolg van vloeistofretensie, naarheid, moegheid en kortasemigheid
- ‘n Uitslag saam met sistemiese simptome soos koors, nagsweet, moegheid, hoes, borskaspyn, swelling, swakheid, verwarring en koma.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese bystand benodig.

Signed:

Lig jou dokter so gou as moontlik in as jy enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- Moegheid, slaperigheid, duiseligheid, gesukkel om jou spiere te beheer, bewerigheid.
- Virale infeksie, respiratoriese infeksie, pneumonie (ernstige longinfeksie. Simptome kan koors, kouekoors, kortasemigheid, hoes, slym en soms bloeding insluit), urienweginfeksie (simptome kan dringende, aanhoudende drang om te urineer, branderige sensasie wanneer urineer, dikwelse passering van klein hoeveelhede urine, urine wat ‘n sterk reuk het, insluit); inflammasie van die oor of ander infeksies;
- Vertigo (duiseligheid of draaiende gevoel in die kop)
- Dubbelvisie, lui-oog, onwillekeurige oogbeweging
- Depressie, dikwelse gemoedsveranderinge
- Spierpyn
- Swelling van die ledemate as gevolg van waterretensie
- Verhoogde aptyt, verlies aan aptyt;
- Verwarring, depressie, emosionele onstabiliteit, senuweeagtigheid, abnormale denke, vyandigheid, angstigheid
- Sukkel om bewegings te kontroleer, duiseligheid, slaperigheid, geheueverlies, abnormale koördinasie, sukkel om te praat, onvermoë om aan die slaap te raak, hoofpyn, nistagmus (vinnige, ongekontrolleerde bewegings van die oë), bewerigheid (rukkings), toevalle, hiperkinese (wanorde by kinders gekenmerk deur hiperaktiwiteit en onvermoë om te konsentreer), sensasies soos parestesie (tintelende of prikkelende, “naalde-en-spelde” sensasie), verlaagde kapasiteit vir fisiese sensasie, veral op die vel, abnormale koördinasie, verhoogde, verlaagde of afwesigheid van reflekse;
- Ambliopie (lui-oog, verlaagde visie in een oog veroorsaak deur abnormale visuele ontwikkeling vroeg in die lewe), dubbelvisie;

Signed:

- Vertigo (draaiende sensasie);
- Verwyding van bloedvate, hipertensie (hoë bloeddruk. Simptome kan erge hoofpyn, neusbloeding, moegheid of verwarring, probleme met sig, borspyn, moeisame asemhaling, onreëlmatige hartklop insluit);
- Hoes, faringitis ('n seer keel en ongemak wanneer gesluk word), rinitis (loop- of toeneus, nies, drukking of pyn in die gesig), dispnee (kortasemigheid), brongitis (inflammasie van die voering van die brongiale buise, wat lug na en van die longe vervoer. Simptome kan hoes, moegheid of algemene siekgevoel, loopneus of post-nasale drip, drukking op die bors, hoofpyn, kortasemigheid, sukkel om te slaap, of seerkeel insluit);
- Buikpyn, hardlywigheid, abnormaliteite van tande, diarree (los stoelgang), slegte spysvertering, droë mond of keel, naarheid en/of braking, gingivitis (algemene en ligte vorm van tandvleissiekte wat irritasie, rooiheid en swelling van die tandvleise veroorsaak, die deel van jou tandvleis rondom die basis van jou tande), winderigheid (oormatige gas in die maag of ingewande);
- Aknee, gejeuk, uitslag, swelling van die gesig, kneusings;
- Rugpyn, spierpyn, rukkings, gewrigspyn;
- Impotensie (probleme met ereksie);
- Moegheid, koors, swelling van die hande, enkels of voete, sukkel om te loop, ongewone swakheid, pyn, algemene siekgevoel, griepagtige simptome (koors of voel koorsig/kry kouekoors, hoes, kortasemigheid of sukkel om asem te haal, moegheid, seerkeel, loop- of verstopte neus, spierpyn of lyfpyne, hoofpyn);
- Gewigstoename;
- Skaafplekke, frakture, toevallige besering.

Minder algemeen:

Signed:

- Hoofpyn, sukkel om woorde uit te spreek, geheueverlies, verwardheid, sukkel om aan die slaap te raak, rukkings, tintelende sensasie, senuweeagtigheid
- Abnormale koördinasie
- Naarheid en braking, sooibrand, ongemak op die maag, droogheid van die mond of keel, hardlywigheid, diarree, tande probleme
- Loopneus, seerkeel, hoes, borsinfeksie
- Aknee, klein, plat, rooi ronde kolletjies op die vel
- Toksiese epidermale nekrolise (uitgebreide afskilfering van die buitenste laag van die vel en binneste laag van die neus en mond)
- Abnormale denke
- Ereksie probleme
- Rugpyn, fraktuur
- Verwyding van bloedvate
- Rooi of pers verkleuring op die vel
- Virale infeksie
- Verhoogde eetlus wat lei tot gewigstoename
- Koors
- Hiperglukemie (verhoging in bloedglukosevlakke. Simptome kan vehoogde dors en/of honger, belemmerde visie, dikwelse urinering (piepie), hoofpyn insluit);
- Hipoglukemie (afname in bloedglukosevlakke. Simptome kan ‘n onreëlmatige of vinnige hartklop, moegheid, bleek vel, wankelrigheid, angstigheid, sweet, honger, geïrriteerdheid insluit);
- Agitasie (toestand van angstigheid of senuweeprikkeling);
- Ongewone verlaagde of stadige liggaamsbeweging, verstandelike inkorting, bewussynsverlies;

Signed:

- Respiratoriese onderdrukking (asemhalingsversteuring gekenmerk deur stadige en oneffektiewe asemhaling);
- Sukkel om te sluk;
- Algemene edeem (swelling wat die gesig, romp en ledemate kan betrek);
- Hiponatremie (lae natriumvlakke in die bloed. Simptome kan spierkrampe of swakheid, naarheid en braking, dooierigheid, of lae energie, hoofpyn en verwarring, veranderinge in geestestoestand, toevalle insluit);
- Hallusinasies (sien, voel of hoor dinge wat nie bestaan nie);
- Onwillekeurige gevroetel en beweging, diskinesie (ongekontrolleerde rukkerige, stamperige of draaiende bewegings), en distonie (ongekontrolleerde spierspasmas wat die oë, kop, nek en lyf affekteer), spastiese stywe nek (wanorde waar die spiere van die nek ongekontroleerd saamtrek, wat veroorsaak dat die nek in verskeie posisies draai) en mioklonus (skielike, onwillekeurige spiertrekking, -trilling of -spasma);
- Tinnitus (gesuis in die ore);
- Geelsug (vergeling van die vel of wit van die oë veroorsaak deur lewer-of bloedprobleme);
- Alopesie (haarverlies);
- Urinêre inkontinensie (verlies aan blaasbeheer, wisselend van ‘n effense lating van urine ná nies, hoes of lag, tot ‘n algehele onvermoë om urinering te kontroleer);
- Borshipertrofie (toestand waarin die borste so groei dat hulle swaar is en probleme veroorsaak), ginekomastie (borsvergroting by mans), seksuele wanfunksie (insluitende veranderinge in seksdrang, vertraagde ejakulasie en onvermoë om seksuele klimaks te bereik);
- Verandering in bloedtoetsresultate
- Mioklonus (seldsame spiertrekkings, lae magnesium of spiermoegheid).

As jy ‘n bejaarde persoon is, kan jy meer sensitief vir hierdie ongewenste reaksies wees.

Signed:

Lig asseblief jou dokter of apteker in as jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad vermeld word nie.

Aanmelding van newe-effekte

Praat met jou gesondheidsorgverskaffer as jy newe-effekte ervaar. Jy kan ook newe-effekte by SAHPRA aanmeld *via* die Med Safety APP (Medsafety X SAHPRA) en eReporting-platform (who-umc.org), wat aanlyn beskikbaar is op SAHPRA se webblad. Deur newe-effekte aan te meld, kan jy meer inligting oor die veiligheid van EPLEPTIN® verskaf.

5. Hoe om EPLEPTIN® te bewaar

- Bewaar by of benede 25 °C.
- Beskerm teen lig en vog.
- Hou die bottel dig toe tot benodig vir gebruik.
- **BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.**
- Moenie die kapsules ná die vervaldatum, soos op die karton aangedui, gebruik nie
- Bring alle ongebruikte medisyne terug na jou apteker toe.
- Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels (bv. toilette) ontslae raak nie.

6. Inhoud van die verpakking en ander inligting

Wat EPLEPTIN® bevat

Die aktiewe bestanddeel is gabapentien.

Elke kapsules bevat gabapentien 100, 300 en 400 mg, onderskeidelik

Die ander bestanddele is: Kalsiumsulfaatdihidraat, voorafgegelatiniseerde stysel, kalsiumkarbonaat, gliserielbehenaat

Samestelling van die kapsule: EPLEPTIN® 100 mg:

Gelatien, water, natriumlourielsulfaat, titaanioksied.

Samestelling van die kapsule: EPLEPTIN® 300 mg:

Gelatien, water, natriumlourielsulfaat, titaandioksied, geel ysteroksied.

Samestelling van die kapsule: EPLEPTIN® 400 mg:

Gelatien, water, natriumlourielsulfaat, titaandioksied, geel ysteroksied, rooi ysteroksied.

Hoe EPLEPTIN® lyk en inhoud van die pakkie

EPLEPTIN® 100 mg: Grootte '3' harde gelatienkapsules, wit dop en wit romp met "137" gedruk in swart op die dop en romp, bevattende 'n wit kristallyne poeier.

EPLEPTIN® 300 mg: Grootte '1' harde gelatienkapsules, geel dop en geel romp met "138" gedruk in swart op die dop en romp, bevattende 'n wit kristallyne poeier.

EPLEPTIN® 400 mg: Grootte '0' harde gelatienkapsules, oranje dop en oranje romp met "139" gedruk in swart op die dop en romp, bevattende 'n wit kristallyne poeier.

EPLEPTIN® 100 mg word verpak in 75 cc wit, ronde plastiekbottels met 33 mm wit geriffelde plastiekdoppies. 100 kapsules per bottel.

EPLEPTIN® 300 mg word verpak in 150 cc wit, ronde plastiekbottels met 38 mm wit geriffelde plastiekdoppies. 100 kapsules per bottel.

EPLEPTIN® 400 mg word verpak in 150 cc wit, ronde plastiekbottels met 38 mm wit geriffelde plastiekdoppies. 100 kapsules per bottel.

STULPSTROOKVERPAKKING 100's: 10 stulpstroke van 10 kapsules per stulpstrook word verpak in 'n silwer aluminium/helder PVC/PVDC- stulpstrook. Tien stulpstroke wat elke tien kapsules bevat, word in 'n buitenste karton verpak.

Signed:

Houer van die registrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14,

Stormill, Uitbreiding 1, Roodepoort

Johannesburg 1724

011 495 0100

Hierdie inligtingstuk was laaste hersien op

Datum van registrasie: 6 Oktober 2006

Datum van hersiening van teks: 9 September 2024

Registrasienommers

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

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

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

Namibië

Skedulering: NS2

EPLEPTIN® 100 mg kapsules: 07/2.5/0090

EPLEPTIN® 300 mg kapsules: 07/2.5/0089

EPLEPTIN® 400 mg kapsules: 07/2.5/0088

Signed: