PATIENT INFORMATION LEAFLET FOR

EPIKEPP 250 / 500 / 750 / 1 000

SCHEDULING STATUS: S3

EPIKEPP 250 / 500 / 750 / 1 000, Film-coated tablets

Levetiracetam

Sugar free

Read all of this leaflet carefully before you start taking EPIKEPP

- 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.
- EPIKEPP 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 EPIKEPP is and what it is used for
2. What you need to know before you take EPIKEPP
3. How to take EPIKEPP
4. Possible side effects
5. How to store EPIKEPP
6. Contents of the pack and other information.

1. What EPIKEPP is and what it is used for

EPIKEPP (Levetiracetam) belongs to a class of medicine known as anticonvulsants, which includes anti-epileptics.

EPIKEPP is indicated as monotherapy for the treatment of partial onset (involving only a part of the brain) seizures (epileptic fits) with or without secondary generalisation in patients over 16 years of age who have been newly diagnosed with epilepsy.

EPIKEPP is indicated as adjunctive therapy

- in the treatment of partial onset seizures with or without secondary generalisation in adults and children over 16 years of age with epilepsy
- in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy
- in the treatment of primary generalised tonic-clonic seizures in adults and children from 16 years of age with idiopathic generalised epilepsy

2. What you need to know before you take EPIKEPP

Do not take EPIKEPP:

- if you are hypersensitive (allergic) to Levetiracetam or other pyrrolidone derivatives, or any of the other ingredients of EPIKEPP (listed in **section 6**).
- if you are pregnant or breast feeding your baby (see **'Pregnancy and breast feeding'**).

Warnings and precautions

Take special care with EPIKEPP:

- Your doctor will decide when to stop treatment with EPIKEPP and when your dose will be gradually reduced over two to four weeks.
- EPIKEPP may cause abnormal behaviour and psychotic symptoms. Patients treated with EPIKEPP should be monitored for psychiatric (mental illness) signs and symptoms.

- Please mention to your doctor if you have weaker or damaged liver or kidney function. If you have kidney problems, your doctor may change your dosage of EPIKEPP. If you have liver problems, you may have to go for blood tests before you receive treatment with EPIKEPP.
- Suicide, suicide attempt and suicidal thoughts have been reported in patients treated with EPIKEPP. Patients should be advised to immediately report any symptoms of depression and/or suicidal thoughts to their prescribing physician (doctor).
- EPIKEPP may cause somnolence (drowsiness) and fatigue (feeling of constant exhaustion, burnout or lack of energy). Patients should be monitored for these signs and symptoms and advised not to drive or operate machinery until they have gained sufficient experience on EPIKEPP to gauge (distance) whether it adversely affects their ability to drive or operate machinery.
- EPIKEPP can cause anaphylaxis (hypersensitivity disorder) or angioedema (swealing below the skin surface) after the first dose or at any time during treatment. Signs and symptoms includes hypotension (low blood pressure), hives, rash, respiratory distress (shortness of breath), and swelling of the face, lip, mouth, eye, tongue, throat, and feet. This can be life-threatening and require emergency treatment. EPIKEPP should be discontinued and you should seek immediate medical attention.
- EPIKEPP can cause serious dermatological reactions, including Stevens-Johnson syndrome [SJS] (disorder of skin and mucous membrane) and toxic epidermal necrolysis [TEN] (life threatening skin condition which peeling and blistering of skin of body including mouth, eyes and private parts. Recurrence of the serious skin reactions. EPIKEPP should be discontinued at the first sign of a rash, unless the rash is clearly not medicine-related. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed and alternative therapy should be considered.

- EPIKEPP can cause Drug (Medicine) Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity. It is fatal (causing or ending in death) or life-threatening if treatment do not occur as early as possible. It can cause fever, rash, lymphadenopathy (swelling of lymph nodes), and/or facial swelling, along with other organ system involvement, such as swelling of liver, swelling of kidney, blood disorder, swelling of heart muscle, or weak, tired and painful muscles, like viral infection. Check for hypersensitivity, such as fever or lymphadenopathy (swelling of lymph nodes), may be present even though rash is absent. If such signs or symptoms are present, the patient should be checked immediately. EPIKEPP should be discontinued if an alternative cause of disease for the signs or symptoms cannot be established.
- EPIKEPP may cause coordination difficulties i.e. the inability to control the position of your arms and legs or your posture.
- EPIKEPP can cause blood or blood related abnormalities. Blood tests to be done in patients experiencing significant weakness, fever, recurrent infections, or coagulation (blood clotting) disorders.

Other medicines and EPIKEPP

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

EPIKEPP does not influence blood levels of other anti-epileptic medicines, such as phenytoin, carbamazepine, valproic acid, phenobarbital, lamotrigine, gabapentin and primidone. These medicines also do not influence the blood levels of EPIKEPP.

Please speak to your doctor if you are also taking probenecid for gout or in combination with certain antibiotics, as probenecid may influence blood levels of one of the break-down products of EPIKEPP. However, this interaction is unlikely to cause a problem.

EPIKEPP does not interfere with the action of oral contraceptives (the pill).
EPIKEPP can be combined with digoxin (for heart failure or heart rhythm problems) and with warfarin (blood thinning agent) as well as with oral contraceptives.
No data on the influence of antacids on the absorption of levetiracetam are available.

EPIKEPP with food, drink and alcohol

Food did not alter the extent of absorption of levetiracetam, but the rate of absorption was slightly reduced.
No data on the interaction of levetiracetam with alcohol are available.

Pregnancy, breastfeeding and fertility

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 EPIKEPP.

Pregnancy

There is no adequate information on the use of EPIKEPP during pregnancy. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown.
Physiological changes during pregnancy may affect EPIKEPP levetiracetam concentration.
There have been reports of decreased levetiracetam concentration during pregnancy.
EPIKEPP is contraindicated in pregnancy.

Breastfeeding

Levetiracetam is excreted in human breast milk. Patients using EPIKEPP should not breastfeed. Safety in breast-feeding has not been established.

Do not use EPIKEPP if you are pregnant or breastfeeding your baby.

Driving and using machines

You may experience excessive sleepiness or other side effects, such as dizziness, when you first start to take EPIKEPP, or when your dosage is increased. Should you experience sleepiness, dizziness or any other side-effect that may impair your ability to drive a car or operate machinery, you should refrain from such activities.

It is not always possible to predict to what extent EPIKEPP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which EPIKEPP affects them.

3. How to take EPIKEPP

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

Always take EPIKEPP exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are ~~unsure~~ not sure.

EPIKEPP should be taken orally, swallowed with liquid. EPIKEPP may be taken with or without food. The daily dose is administered in two equally divided doses.

Swallow the tablet whole. Do not crush, break, or chew the tablet.

Continue to take EPIKEPP for as long as your doctor tells you to, even if you begin to feel better.

If you have the impression that the effect of EPIKEPP is too strong or too weak, tell your doctor

or pharmacist.

Monotherapy

Adults and adolescents from 16 years of age

The recommended starting dose is 250 mg twice daily which should be increased to an initial therapeutic dose of 500 mg twice daily after two weeks. The dose can be further increased by 250 mg twice daily every two weeks depending upon the clinical response. The maximum daily dose is 1 500 mg twice daily.

Add-on therapy

Adults (≥ 18 years) and adolescents (12 to 17 years) weighing 50 kg or more, when indicated

The initial therapeutic dose is 500 mg twice daily. The dose can be started on the first day of treatment.

Depending upon the clinical response and tolerability, the daily dose can be increased up to 1 500 mg twice daily. Dose changes can be made in 500 mg twice daily increases or decreases every two to four weeks.

The maximum daily dose is 3 000 mg.

Adolescents (12 to 17 years) weighing less than 50 kg, when indicated

The initial therapeutic dose is 10 mg/kg twice daily. This dose can be started on the first day of treatment.

The physician should prescribe the most appropriate pharmaceutical form and strength according to weight and dose.

Infants and children less than 12 years

There are insufficient data to recommend the use of EPIKEPP in children under 12 years of age.

Special populations

Elderly (65 years and older)

Adjustment of the dose is recommended in elderly patients with compromised renal function (see 'Patients with renal impairment' below.

If you take more EPIKEPP than you should

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

There is no experience with doses greater than 5 000 mg/day orally. No serious adverse events were reported by healthy volunteers at single doses up to and including 5 000 mg orally. The highest known ingested dose was 6 000 mg, and drowsiness was the only symptom reported in the few known cases of overdosage.

If you have taken a number of EPIKEPP tablets all at once, your stomach will be pumped or you will be given medicines to induce vomiting. There is no specific antidote to EPIKEPP. Your doctor will treat your symptoms and you may have to undergo haemodialysis – a process that removes waste products and certain medicines from the blood which is usually reserved for patients with kidney failure.

If you forget to take EPIKEPP

Take EPIKEPP as prescribed. If you miss a dose of EPIKEPP, take it as soon as possible. However, if you do not remember the missed dose until the next day, skip the missed dose and

go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

If you stop taking EPIKEPP

Your doctor will decide when to stop treatment with EPIKEPP in which instance your dose will be gradually reduced over two to four weeks.

4. Possible side effects

EPIKEPP can have side effects. EPIKEPP may have unintended or undesirable effects.
Not all side effects reported for EPIKEPP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EPIKEPP, please consult your health care provider for advice.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EPIKEPP. 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:

- chest pain,

- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infection, nasopharyngitis.
- Thrombocytopenia.
- Agitation, depression, emotional instability/mood swings, hostility/aggression, insomnia, nervousness/irritability, personality disorders, thinking abnormal.
- Somnolence (sleepiness or unusual drowsiness) predominantly occurs during the first four weeks of treatment.

  Amnesia, ataxia (clumsiness or unsteadiness, problems with muscle control or co-ordination), , convulsions, dizziness, headache, hyperkinesias, tremor, balance disorder, disturbance in attention, memory impairment, vertigo (dizziness or light-headedness, feeling of constant movement of surroundings, sensation of spinning).
- Diplopia (double vision), blurred vision.
- Vertigo.
- Pharyngitis (increased cough, dryness or soreness of throat, fever, hoarseness, runny nose, tender, swollen glands in the neck, trouble in swallowing, voice changes).

- Anorexia (loss of appetite and weight loss), diarrhoea, abdominal pain, dyspepsia and nausea.
- Anorexia, weight increase

  The risk of anorexia is higher when topiramate is co-administered with EPIKEPP.
- Rash, eczema, pruritus.
- Myalgia.
- Headache, asthenia (loss of strength or energy, muscle pain or weakness, unusual weak feeling), infection (fever or chills, cough or hoarseness, lower back or side pain, painful or difficult urination), and fatigue.
- Accidental injury.

Less frequent side effects:

- Anxiety, apathy.
- Emotional lability, hostility, nervousness, paraesthesia (burning, crawling, itching, numbness, prickling, pins and needles or tingling feelings).
- Sinusitis (pain or tenderness around eyes and cheekbones, fever, stuffy or runny nose, headache, cough, shortness of breath or troubled breathing, tightness of chest or wheezing), rhinitis (sneezing, stuffy nose and runny nose).

Side effects with unknown frequency:

- Pancytopenia, leucopenia, neutropenia, pancytopenia (with bone marrow suppression identified in some of the cases), thrombocytopenia.
- Abnormal behaviour, anger, confusion, hallucinations, psychotic disorders.

  Suicide, suicide attempt and suicide ideation.
- Insomnia, tremor.

- Sinusitis (pain or tenderness around eyes and cheekbones, fever, stuffy or runny nose, headache, cough, shortness of breath or troubled breathing, tightness of chest or wheezing), rhinitis (sneezing, stuffy nose and runny nose).
- Pancreatitis.
- Weight loss.
- Toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), erythema multiforme and alopecia.
- Hepatic failure, hepatitis, liver function test abnormal.
- Anaphylaxis and Angioedema: Hypotension, hives, rash, respiratory distress, and swelling of the face, lip, mouth, eye, tongue, throat, and feet.

  Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity: Fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement, such as hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis, sometimes resembling an acute viral infection.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**Adverse drug reaction and quality problem reporting form**", found online under SAHPRA's publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/ or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of EPIKEPP.

5. How to store EPIKEPP

- Store at or below 25 °C.
- This medicine does not require any special storage conditions.
- Store all medicines out of reach of children.
- Keep the blister in the outer carton until required for use.
- Do not use after the expiry date stated 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 EPIKEPP contains

The active substance is Levetiracetam**.**

EPIKEPP 250: Each film-coated tablet contains 250 mg levetiracetam.

EPIKEPP 500: Each film-coated tablet contains 500 mg levetiracetam.

EPIKEPP 750: Each film-coated tablet contains 750 mg levetiracetam.

EPIKEPP 1 000: Each film-coated tablet contains 1 000 mg levetiracetam.

The other ingredients are starch (corn starch 400 L), povidone PVPK – 30, croscarmellose sodium (Ac-di-sol), colloidal unhydrous silica (aerosil 200) and magnesium stearate.

Coating Material

EPIKEPP 250: Opadry Blue 03B50643

EPIKEPP 500: Opadry Yellow 03B52573

EPIKEPP 750: Opadry Pink 03B54276

EPIKEPP 1 000: Opadry White 04F58804

What EPIKEPP looks like and contents of the pack

EPIKEPP 250: Light blue, capsule-shaped, biconvex, film-coated tablets plain on both sides. Supplied in plain aluminium blister foil strip with non-toxic, clear transparent, well thermoformable PVC/PE/PVDC film of 10 tablets packed in 60's per carton.

EPIKEPP 500: Yellow, capsule-shaped, biconvex, film-coated tablets plain on both sides. Supplied in plain aluminium blister foil strip with non-toxic, clear transparent, well thermoformable PVC/PE/PVDC film of 10 tablets packed in 60's per carton.

EPIKEPP 750: Pink, capsule-shaped, biconvex, film-coated tablets plain on both sides. Supplied in plain aluminium blister foil strip with non-toxic, clear transparent, well thermoformable PVC/PE/PVDC film of 10 tablets packed in 60's per carton.

EPIKEPP 1 000: White, capsule-shaped, biconvex, film-coated tablets plain on both sides. Supplied in plain aluminium blister foil strip with non-toxic, clear transparent, well thermoformable PVC/PE/PVDC film of 10 tablets packed in 30's per carton.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.