KEPPRA® TABLETS
Patient Information Leaflet

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

KEPPRA® 250 mg film-coated tablets

KEPPRA® 500 mg film-coated tablets

KEPPRA® 750 mg film-coated tablets

KEPPRA® 1 000 mg film-coated tablets

Read all of this leaflet carefully before you start taking KEPPRA.

Keep this leaflet. You may need to read it again.

If you have any questions, please ask your doctor or pharmacist.

KEPPRA has been prescribed for you personally, and should not be shared with other people. It may harm them, even if their symptoms are the same as yours.

WHAT KEPPRA CONTAINS:

The active substance is levetiracetam.

Each film-coated tablet contains 250 mg, 500 mg, 750 mg, or 1000 mg of levetiracetam.

The other ingredients are: sodium croscarmellose, macrogol 6 000, colloidal anhydrous silica, magnesium stearate, polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc and the additional agents listed below:

- 250 mg tablets: Indigo carmine aluminium lake (E132)
- 500 mg tablets: iron oxide yellow (E172)
- 750 mg tablets: sunset yellow FCF aluminium lake (E110), iron oxide red (E172).

WHAT KEPPRA IS USED FOR:

KEPPRA is an anti-epileptic medicine (a medicine used to treat seizures in epilepsy).

KEPPRA is used alone in the treatment of partial seizures in patients from 16 years of age.

KEPPRA is used in patients who are already taking another anti-epileptic medicine.

- In the treatment of partial 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 with idiopathic generalised epilepsy.

BEFORE YOU TAKE KEPPRA:

Do not take KEPPRA:

Before taking this medicine, you should tell your doctor:

- If you are hypersensitive (allergic) to levetiracetam or any of the other ingredients of KEPPRA stated at the beginning of this leaflet.
- If you are pregnant or breastfeeding your baby.

Take special care with KEPPRA:

- If you suffer from kidney problems, follow your doctor's instructions. They may decide that your dose should be adjusted.
- If your treatment has to be stopped, your doctor will tell you how to withdraw it gradually.
- KEPPRA tablets have not been approved for children below the age of 12 years.

Taking KEPPRA with food and drink

You may take KEPPRA with or without food.

Caution is advised if alcohol is taken at the same time as KEPPRA.

Pregnancy and Breastfeeding:

KEPPRA should not be used when you are pregnant.

You should not breastfeed your baby if you are using KEPPRA.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, before taking KEPPRA.

Driving and using machinery:

KEPPRA may make you dizzy or sleepy.

Do not drive, operate any tools or machines until you know how KEPPRA affects you.

Taking other medicines with KEPPRA:

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

HOW TO TAKE KEPPRA:

Always take KEPPRA exactly as your doctor has told you. You should check with your doctor, pharmacist or other healthcare professional if you are unsure.

If you think that the effect of KEPPRA is too strong or too weak, talk to your doctor or pharmacist.

The film-coated tablets must be taken orally (by mouth), swallowed with liquid and may be taken with or without food. The daily dose must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

When KEPPRA is used alone:

***Adults and adolescent 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 as determined by your doctor. The maximum daily dose is 1 500 mg twice daily. The dose specific for you, will be determined by your doctor and you should follow his/her instructions carefully.

When KEPPRA is used in combination with other anti-epileptic medicine: Your doctor will advise on the correct dose.

Your doctor, pharmacist or other healthcare professional may start you on a lower dose of KEPPRA and increase it as your body gets used to the medicine. You should follow their instructions carefully.

Tell your doctor, pharmacist or other healthcare professional if your seizures get worse or if you have any new types of seizures.

Duration of treatment:

- KEPPRA is used as a chronic treatment. You should continue KEPPRA treatment for as long as your doctor told you.

If you take more KEPPRA than you should:

Signs of taking too much KEPPRA are increased sleepiness, anxiety, decreased consciousness and difficulty breathing.

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

If you forget to take KEPPRA:

Contact your doctor if you have missed one or more doses.

Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with KEPPRA is stopped:

Do not stop your treatment without your doctor's advice as this could increase your seizures. Should your doctor decide to stop your KEPPRA treatment, they will instruct you about the gradual withdrawal of KEPPRA.

POSSIBLE SIDE EFFECTS:

KEPPRA can have side effects.

Not all side effects reported for KEPPRA are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking KEPPRA, please consult your doctor pharmacist or healthcare professional for advice.

Tell your doctor, pharmacist or other healthcare professional if you have any of the following side effects.

Frequent side effects with use of KEPPRA

- sleepiness
- tiredness
- dizziness, convulsions, headache, hyperactivity, impaired coordinated movement, involuntary trembling, loss of memory, balance disorder, loss of concentration and forgetfulness

- anxiety, depression, mood swings, aggression, sleeping problems, irritability, behavioural problems, slow thinking or unable to concentrate
- diarrhoea, indigestion, abdominal pain, nausea, vomiting
- loss of appetite, weight increase
- vertigo (sensation of rotation)
- double vision, vision blurred
- muscle pain
- accidental injury
- increase of pre-existing cough
- rash, eczema, itching
- decreased number of blood platelets.

Other side effects reported with the use of KEPPRA:

- tingling sensation (‘pins and needles’)
- confusion, hallucination (a false sense of perception), suicide, suicide attempt or suicidal thoughts
- inflammation of the pancreas or liver, liver failure, or abnormal liver test results
- blistering of the skin, mouth, eyes and genital area, skin eruption, hair loss
- decreased number of red blood cells and/or white blood cells.

If any of these side effects get serious, please tell your doctor or pharmacist immediately.

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

STORING AND DISPOSING OF KEPPRA:

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use after the expiry date stated on the pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF KEPPRA:

KEPPRA 250 mg film-coated tablets are packed in aluminium/PVC blisters in cardboard boxes containing 20, 30, 50, 60 and 100 tablets.

KEPPRA 500 mg film-coated tablets are packed in aluminium/PVC blisters in cardboard boxes containing 10, 20, 30, 50, 60,100, 120 & 200 tablets.

KEPPRA 750 mg film-coated tablets are packed in aluminium/PVC blisters in cardboard boxes containing 20, 30, 50, 60, 80 and 100 tablets.

KEPPRA 1000 mg film-coated tablets are packed in aluminium/PVC blisters in cardboard boxes containing 20, 30, 50, 60,100, 120 & 200 tablets.

IDENTIFICATION OF KEPPRA:

KEPPRA 250 mg film-coated tablets are blue oblong film-coated, scored tablets debossed with the code ucb-250 on one side.

KEPPRA 500 mg film-coated tablets are yellow oblong film-coated, scored tablets debossed with the code ucb-500 on one side.

KEPPRA 750 mg film-coated tablets are orange oblong film-coated, scored tablets debossed with the code ucb-750 on one side.

KEPPRA 1000 mg film-coated tablets are white oblong film-coated, scored tablets debossed with the code ucb-1000 on one side.

REGISTRATION NUMBER:

1.3.2 Patient Information Leaflet

KEPPRA 250 mg film-coated tablets 36/2.5/0088

KEPPRA 500 mg film-coated tablets 36/2.5/0089

KEPPRA 750 mg film-coated tablets 36/2.5/0090

KEPPRA 1000 mg film-coated tablets 36/2.5/0091

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

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Amended: Transfer of applicancy to GSK – approved 11 November 2010
Amended: 12 April 2011 in-line with PDS04

Amended: 16 January 2013 (in line with CCC recommendations dated 17/08/2012) – annotated
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Amended: 30 January 2014 (safety update NCDSv1-5) – safety update in process with MCC
Amended: 27 January 2015 (to bring in line with PI guideline v5) - notification