KEPPRA Oral Solution

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

KEPPRA® 100 mg oral solution

Levetiracetam

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

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

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

KEPPRA 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 KEPPRA CONTAINS:

The active substance is called levetiracetam.

Each ml of oral solution contains 100 mg levetiracetam.

Preservatives: methylparahydroxybenzoate 0,027 % *m/v* and propylparahydroxybenzoate 0,003 % *m/v.*

Contains sugar (as maltitol 300 mg/ml).

Contains sweetener (as acesulfame potassium 4,50 mg/ml)

The other ingredients are sodium citrate, citric acid monohydrate, ammonium glycyrrhizinate, glycerol, grape flavour and purified water.

WHAT KEPPRA IS USED FOR:

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

KEPPRA is used in patients who are already taking another anti-epileptic medicine, to treat partial seizures in adults and children over 4 years of age with 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 to any of the other ingredients of KEPPRA stated at the beginning of this leaflet
- if you are pregnant or breastfeeding your baby
- if you are allergic to fructose you should not use KEPPRA oral solution.

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 has not been approved for children below the age of 4 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:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or

other healthcare professional for advice, before taking KEPPRA.

KEPPRA should not be used during pregnancy.

KEPPRA should not be taken during breastfeeding since it can pass into your breast milk and may harm your baby.

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.

Important information about some of the ingredients of KEPPRA:

KEPPRA contains glycerol and maltitol which can cause headache, stomach upset and diarrhoea.

KEPPRA contains maltitol. If you have been told that you have an intolerance to some sugars, you should not take KEPPRA.

Taking other medicines with KEPPRA:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of KEPPRA with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other healthcare professional for advice.

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.

Tablets are also available for adults and adolescents that can swallow tablets.

The oral solution should be diluted in a glass of water and may be taken with or without food.

A graduated oral syringe and instructions for use in the patient information leaflet are provided with the oral solution. The daily dose is administered in two equal divided doses.

Adults (> 18 years) and adolescents (12 to 17 years):

As adjunctive therapy, the initial therapeutic dose is 500 mg twice daily. This dose can be started on the first day of treatment. Depending upon the clinical response and tolerance, the daily dose can be increased up to 1500 mg twice daily. Dose changes can be made in 500 mg twice daily increments or decrements every two to four weeks. The maximum daily dose is 3000 mg.

***Elderly (65 years and older)*:**

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

Children aged 4 to 11 years:

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

Depending upon the clinical response as determined by your doctor, and how well you tolerate KEPPRA, the daily dose can be increased up to 30 mg/kg twice daily. Dose changes can be made in 10 mg/kg twice daily increments or decrements every two weeks. Dosage in children 50 kg or greater is the same as in adults.

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.

Administration:

KEPPRA oral solution has to be diluted in a glass of water.

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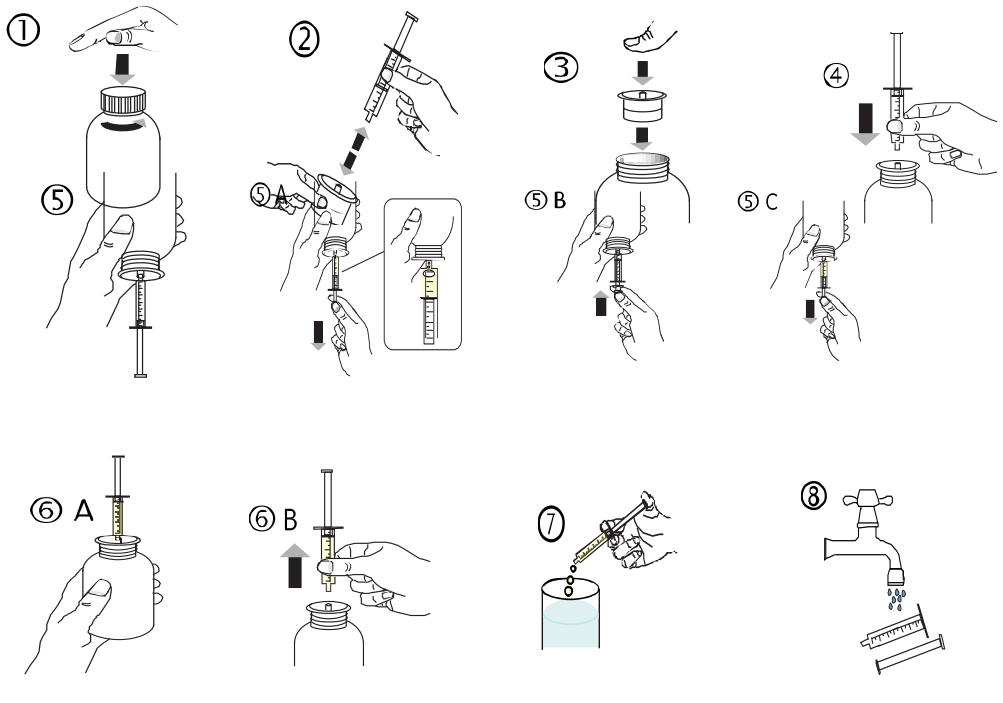
Instruction for use:

- Open the bottle: press the cap and turn it anticlockwise (figure 1).
- Insert the syringe adaptor into the bottle neck (figure 3). Ensure it is well fixed
- Take the syringe and put it in the adaptor opening (figure 4).
- Turn the bottle upside down (figure 5).
- Fill the syringe with a small amount of liquid by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B), finally pull the piston down to the graduation mark corresponding to the quantity in milligrams (mg) prescribed by your doctor (figure 5C).
- Turn the bottle the right way up (figure 6). Remove the syringe from the adaptor (figure 6A).
- Empty the contents of the syringe in a glass of water by pushing the piston to the bottom (figure 7).
- Drink the whole contents of the glass.
- Wash the syringe in water (figure 8).
- Close the bottle with the plastic screw cap.

1.3.2 Patient Information Leaflet



Duration of treatment:

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

If you take more KEPPRA than you should:

Talk to your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

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

If you forget to take KEPPRA:

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

Speak to your doctor, pharmacist or other healthcare professional about what to do if you miss a dose.

Effects when treatment with KEPPRA is stopped:

Do not stop treatment without your doctor's advice as this could increase your seizures. Should your doctor decide to discontinue 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 while taking KEPPRA, please consult your doctor, pharmacist or other healthcare professional for advice.

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

Most frequent side effects reported with KEPPRA are:

- somnolence (sleepiness)
- asthenia (tiredness).

Other side effects reported with KEPPRA are:

- nervous system disorders: dizziness (sensation of unsteadiness), convulsion, headache, hyperkinesias (hyperactivity), ataxia (impaired coordinated movements), tremour (involuntary trembling), amnesia (loss of memory), balance disorder, disturbance in attention, memory impairment, tingling ('pins and needles')

- psychiatric disorders: agitation, abnormal behaviour, aggression, anger, anxiety, confusion, depression, emotional instability/mood swings, hallucination, hostility, insomnia, irritability or nervousness and mental disorder, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate), suicide attempt or suicidal thinking
- digestive disorders: abdominal pain, nausea, dyspepsia (indigestion), diarrhoea, vomiting, pancreatitis
- hepatobiliary disorders: inflammation of the liver, liver failure or abnormal liver test results
- nutrition disorders: anorexia (loss of appetite)
- ear and labyrinth disorders: vertigo (sensation of rotation)
- eye disorders: diplopia (double vision), blurred vision
- injury: accidental injury
- respiratory disorders: increased cough
- skin disorders: rash, eczema, pruritus (itching), alopecia (hair loss), blistering of the skin, mouth, eyes or genital area, skin eruption
- blood disorders: decreased number of red blood cells, white blood cells and/or blood platelets.

Some of the side effects like sleepiness, tiredness and dizziness may be common at the beginning of treatment or at dosage increase.

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

STORAGE AND DISPOSING OF KEPPRA:

Keep all medicines out of the reach and sight of children.

Due to sensitivity to light, store in the original container.

Store at or below 30 °C.

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

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 100 mg/ml oral solution is supplied in a 300 ml amber glass bottle with a white plastic child-resistant cap. It is packed in a cardboard box and may or may not a 10 ml graduated syringe and an adaptor for the syringe.

IDENTIFICATION OF KEPPRA:

A clear and colourless solution with a grape flavour.

REGISTRATION NUMBER:

A 40/2.5/0587

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION:

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Revision approval date: 11 October 2013

Date of implementation of Regulation 12: 21 February 2018

1.3.2 Patient Information Leaflet

PDS-04

HISTORY:

Approved October 2009
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Amended: 12 April 2011 in-line with PDS04
Amended: 16 January 2013 (in line with CCC recommendation dated 17/08/2012) – annotated
Amended: 06 June 2013 (in line with CCC recommendations 08/04/2013) – clean
Amended: 06 August 2013 (in line with CCC recommendations dated 30/07/2013) – **App 11/10/2013**
Amended: 19 January 2012 (CMC - D2011-3869 – inclusion of adaptor). **Approved 10 Jun 2014**
Amended: 18 July 2016 (CMC – Type: B4a; D2014-8015.v0002 – CTD rebaseline dossier). Implemented 16-08-2016

Amended: 20 Feb 2018 (to bring in line with Regulation 11/12 of Act 101/1965 as amended). Implemented 21-Feb-2018