# KEPPRA FILM COATED TABLET / ORAL SOLUTION

Levetiracetam (250mg, 500mg, 1000mg, 100mg/ml)

**What is in this leaflet**



**What KEPPRA is used for**

Keppra is used:

- on its own in adults and adolescents from 16 years of age with a certain type of newly diagnosed epilepsy. Epilepsy is a condition where the patients have repeated fits (seizures). Levetiracetam is used for the epilepsy form in which the fits initially affect only one side of the brain, but could thereafter extend to larger areas on both sides of the brain (partial onset seizures with or without secondary generalization). Keppra has been given to you by your doctor to reduce the number of fits.
- as an add-on to other antiepileptic medicines to treat:
  - partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy.
  - myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
  - primary generalized tonic-clonic seizures (major fits, including loss of consciousness) in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.

**How KEPPRA works**

Keppra is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

**Before you use KEPPRA**

- *When you must not use it*

Do not take Keppra

- If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine (see section **Product Description**).

*Pregnancy and breastfeeding:*

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Keppra should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child cannot be completely excluded. Keppra has shown unwanted reproductive effects in animal studies.

Breast-feeding is not recommended during treatment.

*Children and adolescents*

Keppra is not indicated in children and adolescents before 16 years on its own (monotherapy).

- *Before you start to use it*

Talk to your doctor before taking Keppra

- If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.
- If you notice any slowdown in the growth or unexpected puberty development of your child, please contact your doctor.
- A small number of people being treated with anti-epileptics such as KEPPRA have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**How to use KEPPRA**

- *How much to use*

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take the number of tablets following your doctor's instructions.

*Monotherapy:*

Dose in adults and adolescents (from 16 years of age):

General dose: between 1000 mg and 3,000 mg each day.

When you will first start taking Keppra, your doctor will prescribe you a lower dose during 2 weeks before giving you the lowest general dose.

*Add-on therapy:*

Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more:

General dose: between 1,000 mg and 3,000 mg each day.

Dose in children (4 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg:

Your doctor will prescribe the most appropriate pharmaceutical form of Keppra according to the age, weight and dose.

Keppra 100 mg/ml oral solution is a presentation more appropriate to children under the age of 6 years and to children and adolescent (from 6 to 17 years) weighing less than 25kg and when tablets don't allow accurate dosage.

The exact quantity of oral solution formulation should be delivered using the syringe provided in the cardboard box.

| Weight | Starting dose: 0.1 ml/kg twice daily | Maximum dose: 0.3 ml/kg twice daily |
|---|---|---|
| 10 kg | 1 ml twice daily | 3 ml twice daily |
| 15 kg | 1.5 ml twice daily | 4.5 ml twice daily |

| | | |
|---|---|---|
| 20 kg | 2 ml twice daily | 6 ml twice daily |
| 25 kg | 2.5 ml twice daily | 7.5 ml twice daily |
| From 50 kg | 5 ml twice daily | 15 ml twice daily |

Swallow Keppra tablets with a sufficient quantity of liquid (e.g. a glass of water).

***Keppra oral solution***
*Method of administration:*
Keppra oral solution may be diluted in a glass of water. You may take Keppra with or without food.

- *When to use it*

Keppra must be taken twice a day, once in the morning and once in the evening, at about the same time each day. You may take Keppra with or without food.

- *How long to use it*

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

Do not stop your treatment without your doctor's advice as this could increase your seizures. If stopping treatment, Keppra should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your Keppra treatment, he/she will instruct you about the gradual withdrawal of Keppra.

- *If you forget to use it*

Contact your doctor if you have missed one or more doses. Do not take a double dose to make up for a forgotten tablet.

- *If you use too much (overdose)*

The possible side effects of an overdose of Keppra are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.

Contact your doctor if you took more tablets than you should. Your doctor will establish the best possible treatment of overdose.

**While you are using it**
- *Things you must do*

Take your medicine exactly as your doctor has told you.

Keppra oral solution may be diluted in a glass of water or baby's bottle.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not give Keppra to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

*Driving and using machines*
Keppra may impair your ability to drive or operate any tools or machinery, as Keppra may make you sleepy. This is more likely at the beginning of treatment or after an increase in the dose. You should not drive or use machines until it is established that your ability to perform such activities is not affected.

Keppra oral solution includes methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Keppra oral solution also contains maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**Side effects**
Like all medicines, this medicine can cause side effects, although not everybody gets them. The most frequently reported side effects are nasopharyngitis, somnolence (sleepiness), headache, fatigue and dizziness. At the beginning of the treatment or at dose increase side effects like sleepiness, tiredness and dizziness may be more common. These effects should however decrease over time.

*Very common: may affect more than 1 user in 10 people*
- nasopharyngitis (common cold);
- somnolence (sleepiness), headache.

*Common: may affect 1 to 10 users in 100 people*
- anorexia (loss appetite);
- depression, hostility or aggression, anxiety, insomnia, nervousness or irritability;
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy (lack of energy and enthusiasm), tremor (involuntary trembling);
- vertigo (sensation of rotation);
- cough;
- abdominal pain, diarrhea, dyspepsia (indigestion), vomiting, nausea;
- rash;
- asthenia/fatigue (tiredness).

*Uncommon: may affect 1 to 10 users in 1000 people*
- decreased number of blood platelets, decreased number of white blood cells;
- weight decrease, weight increase;
- suicide attempt and suicidal ideation, mental disorder, abnormal behavior, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation;
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordination movements), paraesthesia (tingling), disturbance in attention (loss of concentration);
- diplopia (double vision), vision blurred;
- elevated/abnormal values in a liver function test;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);
- injury.

*Rare: may affect 1 to 10 users in 10,000 people*
- infection;
- decreased number of all blood cell types;

- severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction];
- decreased blood sodium concentration;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesias (hyperactivity);
- pancreatitis (pancreas inflammation);
- liver failure, hepatitis;
- skin rash, which may form blisters and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form causing skin peeling in more than 30% of the body surface (*toxic epidermal necrolysis*).

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything in this list.

Tell your doctor immediately if you notice any of the following:

- Symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, may be a sign of sudden decrease of kidney function.
- Signs or symptoms including muscleache, feeling of weakness and dark urine may indicate the side effect of rhabdomyolysis (breakdown of muscle tissue).
- If someone around you notices signs of confusion, somnolence (sleepiness}, amnesia (loss of memory), memory impairment (forgetfulness), abnormal behaviour or other neurological signs including involuntary or uncontrolled movements, these could be symptoms of an encephalopathy.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI).

**Storage and Disposal of KEPPRA**

- *Storage*

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date stated on the carton box and blister after EXP.
The expiry date refers to the last day of the month.

*Tablets*
250mg: Store below 25°C.
500mg: Store below 30°C.
1000mg: Store below 30°C.

*Oral solution*
Store below 30°C.

- *Disposal*

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**Product Description**

- *What it looks like*

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

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

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

Keppra Oral Solution 100mg/ml is a clear liquid

- *Ingredients*

- Active ingredient(s)

Levetiracetam (250mg, 500mg or 1000mg per tablet)

- Inactive ingredients:

Tablet core: Sodium Croscarmellose, Macrogol 6000, Colloidal anhydrous silica, Magnesium stearate
Coating material:
250mg: Opadry 85F20694 Blue
500mg: Opadry 85F32004 Yellow
1000mg: Opadry 85F18422 White

Oral solution:
Grape flavor Firmenich 501040A, ammonium glycyrrhizate, maltitol liquid, sodium citrate, acesulfame potassium, glycerol 85 per cent, propyl parahyroxybenzoate, citric acid monohydrate, methyl parahydroxybenzoate, purified water.

- *MAL number(s):*

Keppra 250 mg film-coated tablet
MAL20031725ARZ

Keppra 500 mg film-coated tablet
MAL20031726ARZ

Keppra 1000 mg film-coated tablet
MAL20031727ARZ

Keppra Oral Solution 100mg/ml
MAL07122776ACRZ

**Manufacturer**

*Tablets*
UCB S.A. Sector Pharma
Chemin-du Foriest, B-1420,
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*Oral solution*
Nextpharma SAS
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**Product Registration Holder**
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