Package Leaflet:
Information for the patient

Keppra® 500 mg

film-coated tablets
Levetiracetam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet

What is in this leaflet:

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

1. What Keppra is and what it is used for

Keppra 500 mg film-coated tablets are an antiepileptic medicine (a medicine used to treat seizures in epilepsy).
Keppra is used:

- on its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat partial onset seizures with or without secondary generalisation.
- as an add-on to other antiepileptic medicines to treat:
  - partial onset seizures with or without generalisation in adults, adolescents, children and infants from one month of age
  - myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
  - primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with idiopathic generalised epilepsy

2. What you need to know before you take Keppra

Do not take Keppra

- If you are allergic (hypersensitive) to levetiracetam or any of the other ingredients of this medicine (listed in Section 6).

Warnings and Precautions

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 slow down in the growth or unexpected puberty development of your child, please contact your doctor.
- If you notice an increase in seizure severity (e.g. increased number), 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.

Other medicines and Keppra

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Keppra with food, drink and alcohol

You may take Keppra with or without food. As a safety precaution, do not take Keppra with alcohol.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or if you think you may be pregnant, please inform your doctor.

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 at dose levels higher than you would need to control your seizures.

Breast-feeding is not recommended during treatment.

Driving and using machines

Keppra may impair your ability to drive or operate any tools or machinery, as Keppra may make you feel 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.

3. How to take Keppra

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Keppra must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

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 (2 tablets) and 3,000 mg (6 tablets) 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.

Example: if your daily dose is 2,000 mg, you must take 2 tablets in the morning and 2 tablets in the evening.

Add-on therapy

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

General dose: between 1,000 mg (2 tablets) and 3,000 mg (6 tablets) each day.

Example: if your daily dose is 1,000 mg, you must take one tablet in the morning and one tablet in the evening.

Dose in infants (6 to 23 months), children (2 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 infants and children under the age of 6 years.

General dose: between 20 mg per kg bodyweight and 60 mg per kg bodyweight each day.

Dose in infants (1 month to less than 6 months):

Keppra 100 mg/ml oral solution is a presentation more appropriate to infants.

Method of administration:

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

Duration of treatment:

- 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. Should your doctor decide to stop your Keppra treatment, he/she will instruct you about the gradual withdrawal of Keppra.

If you take more Keppra than you should:

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.

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 a forgotten tablet.

If you stop taking Keppra:

If stopping treatment, as with other antiepileptic medicines, Keppra should be discontinued gradually to avoid an increase of seizures.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some of the side effects like sleepiness, tiredness and dizziness may be more common at the beginning of the treatment or at dose increase. These effects should however decrease over time.

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

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

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

Rare: may affect 1 to 10 users in 10,000
- infection;
- decreased number of all blood cell types;
- 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, hyperkinesia (hyperactivity);
- pancreatitis;
- hepatic failure, hepatitis;
- skin rash, which may form blisters and looks 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)*.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Keppra

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.

This medicine does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Keppra contains

The active substance is called levetiracetam. Each tablet contains 500 mg of levetiracetam.

The other ingredients are:

Tablet core: croscarmellose sodium, macrogol 6000, silica colloidal anhydrous, magnesium stearate.

Film-coating: Opadry 85F32004 (Polyvinyl alcohol-part. Hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172)).

What Keppra looks like and contents of the pack

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

The cardboard boxes contain 10, 20, 30, 50, 60, 100 x 1, 100, 120 film-coated tablets and multipacks containing 200 (2 packs of 100) film-coated tablets. The 100 x 1 tablet pack is available in aluminium/PVC perforated unit dose blisters. All other packs are available in standard aluminium/PVC blisters. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
UCB Pharma SA, Allée de la Recherche 60, B-1070 Brussels, Belgium.

Manufacturer:
UCB Pharma SA, Chemin du Foriest, B-1420 Braine-l'Alleud, Belgium.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu