PACKAGE LEAFLET: INFORMATION FOR THE USER

Keppra

Keppra 250 mg film-coated tablets

Keppra 500 mg film-coated tablets

Keppra 750 mg film-coated tablets

Keppra 1000 mg film-coated tablets

LEVETIRACETAM

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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

Levetiracetam is 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 a certain form of 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 seizure with or without secondary generalisation). Levetiracetam 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 generalisation in adults, adolescents, children and infants from one month of age;
- 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 generalised tonic-clonic seizures (major fits, including loss of consciousness) in adults and adolescents from 12 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KEPPRA

Do not take Keppra

• If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions

Talk to your doctor before taking Keppra 1

• 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.

• 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.

Children and adolescents

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

Other medicines and Keppra

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

Do not take macrogol (a drug used as laxative) for one hour before and one hour after taking levetiracetam as this may results in a loss of its effect.

Pregnancy and breast-feeding

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 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 it 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.

Keppra 750 mg tablets contain Sunset Yellow FCF (E110).

Sunset Yellow FCF (E110) colouring agent may cause allergic reactions.

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.

Take the number of tablets following your doctor's instructions.
Keppra must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

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.
Example: if your daily dose is 1000 mg, your reduced starting dose is 2 tablets of 250 mg in the morning and 2 tablets of 250 mg 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 and 3,000 mg each day.
  Example: if your daily dose is 1,000 mg, you might take 2 tablets of 250 mg in the morning and 2 tablets of 250 mg in the evening.

- Dose in infants (1 month 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 formulation more appropriate to infants and children under the age of 6 years and to children and adolescent (from 6 to 17 years) weighing less than 50kg and when tablets don't allow accurate dosage.

Method of administration

Swallow Keppra tablets with a sufficient quantity of liquid (e.g. a glass of water). You may take Keppra with or without food.

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.

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, 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 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.

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;
- somnolence (sleepiness), headache.

Common: may affect 1 to 10 users in 100 people

- anorexia (loss of 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, diarrhoea, 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 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;
- 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], Quincke's oedema [swelling of the face, lips, tongue and throat]);
- 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, hyperkinesia (hyperactivity);
• pancreatitis;
• liver 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).

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

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.
One tablet of Keppra 250 mg contains 250 mg of levetiracetam.
One tablet of Keppra 500 mg contains 500 mg of levetiracetam.
One tablet of Keppra 750 mg contains 750 mg of levetiracetam.
One tablet of Keppra 1,000 mg contains 1,000 mg of levetiracetam.

The other ingredients are:

Tablet core: croscarmellose sodium, macrogol 6000, silica colloidal anhydrous, magnesium stearate.
Film-coating: Polyvinyl alcohol-part. hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, colourants*.

** The colourants are:*

250 mg tablet: indigo carmine aluminium lake (E132)
500 mg tablet: iron oxide yellow (E172)
750 mg tablet: sunset yellow FCF (E110), iron oxide red (E172)

What Keppra looks like and contents of the pack

Keppra 250 mg film-coated tablets are blue, 13 mm oblong, scored and debossed with the code “ucb” and “250” on one side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Keppra 500 mg film-coated tablets are yellow, 16 mm oblong, scored and debossed with the code “ucb” and “500” on one side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Keppra 750 mg film-coated tablets are orange, 18 mm oblong, scored and debossed with the code “ucb” and “750” on one side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Keppra 1000 mg film-coated tablets are white, 19 mm oblong, scored and debossed with the code “ucb” and“1000” on one side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Keppra tablets are packaged in blister packs supplied in cardboard boxes containing:

• 250 mg: 20, 30, 50, 60, 100 x 1, 100 film-coated tablets and multipacks containing 200 (2 packs of 100) film-coated tablets

• 500 mg: 10, 20, 30, 50, 60, 100 x 1, 100, 120 film-coated tablets and multipacks containing 200 (2 packs of 100) film-coated tablets

• 750 mg: 20, 30, 50, 60, 80, 100 x 1, 100 film-coated tablets and multipacks containing 200 (2 packs of 100) film-coated tablets

• 1000 mg: 10, 20, 30, 50, 60, 100 x 1, 100 film-coated tablets and multipacks containing 200 (2 packs of 100) film-coated tablets

The 100 x 1 tablet packs are 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

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.
or Aesica Pharmaceuticals S.r.l., Via Praglia 15, I-10044 Pianezza, Italy

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