PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Keppra 250 mg coated tablets

Keppra 500 mg coated tablets

Keppra 1000 mg coated tablets

The active ingredient and its quantity:
Each tablet of Keppra 250 mg contains:
Levetiracetam 250 mg
Each tablet of Keppra 500 mg contains:
Levetiracetam 500 mg
Each tablet of Keppra 1000 mg contains:
Levetiracetam 1000 mg
For a list of inactive ingredients and allergens - see section 6.

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine.
If you have any other questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.
This medicine is not intended for use in babies and children under 4 years of age.

1. What is the medicine intended for?

1. As monotherapy in different types of epilepsy in adults from 16 years of age.
2. As adjunctive therapy to other anti-epileptic medicines in:
- Adult and children patients from 4 years of age with different types of epilepsy.
- Adult and adolescent patients from 12 years of age with Juvenile Myoclonic Epilepsy or Idiopathic Generalized Epilepsy.

Therapeutic class: The active ingredient belongs to the anticonvulsants group.

2. Before using the medicine:

Do not use this medicine if:

- You are sensitive (allergic) to Levetiracetam or other Pyrrolidone derivatives or any of the additional components the medicine contains (See section 6 below).

Special warnings regarding the use of the medicine:
- **Before treatment with Keppra, inform the doctor if:**
- You suffer from renal impairment. The doctor may change the medicine's dosage.
- If you observed slower growth or unexpected puberty of your child, contact the attending doctor.
- If during the treatment seizures frequency increases (e.g. their number rises), contact the attending doctor.
- You experience symptoms of depression and/or suicidal thoughts. A small number of people who were treated with anti-epileptic medicines such as Keppra have experienced suicidal or destructive thoughts towards themselves.

Taking anticonvulsants may increase the risk for suicidal actions or thoughts.
You and your family members must pay attention to changes in mood and behavior patterns. Watch for signs indicating risk of suicide, such as: talking or thinking about wanting to hurt yourself, introversion and withdrawal from family and friends, depression or worsening of existing depression, preoccupation with the subject of death, abandoning or giving away prized possessions.
- One of the following side effects worsens or persists for more than a few days: unusual thoughts, irritability or more aggressive reactions than usual, or if you or your family and people around you observe significant changes in your mood or behavior.

In case one or more of these signs or any other alarming behavioral pattern appears – contact the doctor immediately!

Children and adolescents
Keppra is not intended to be a monotherapy for children and adolescents under the age of 16.

Drug-drug interactions:
If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially if you are taking:
- Macrogol (laxative). Do not take Macrogol for an hour before or after taking Keppra, since it may reduce the medicine's efficiency.
- Temozolomide. Liver function should be evaluated before starting a combination therapy of temozolomide and Keppra. In case a combination therapy has been decreed, liver function tests should be performed regularly during therapy and termination of the combined therapy should be considered as necessary.

Use of the medicine and food
The tablets should be taken with a sufficient amount of water (a glass of water). The medicine may be taken with or without food. After taking this medicine, you may feel a bitter taste.

Use of the medicine and alcohol consumption
No data is available regarding an interaction between alcohol and this medicine.

❗ Pregnancy, breastfeeding and fertility
If you are pregnant, breastfeeding, thinking you might be pregnant or planning to become pregnant, you should consult the doctor before taking this medicine. Keppra may be used during pregnancy, if after careful evaluation the doctor deems this treatment necessary. Do not stop the treatment without consulting a doctor. The risk of causing congenital malformations in the fetus cannot be completely ruled out.
Breastfeeding is not recommended during treatment with Keppra.
❗ Driving and operating machinery
Keppra may impair your ability to drive or operate heavy machinery, because you might feel drowsy. This effect occurs primarily in the beginning of treatment and after increasing the dose. Do not drive or operate heavy machinery until you feel fit to perform these actions.
Children should be cautioned against riding a bicycle or playing near a road etc.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined by the doctor only.
Do not exceed the recommended dose.
Method of administration
The tablets should be taken with a sufficient amount of water (a glass of water).
The daily dose should be divided into 2 identical doses; one dose should be taken in the morning and one in the evening. Be sure to take the medicine at the same time every day.
Keppra tablets is not appropriate for use in children under 6 years of age, due to swallowing difficulties. Keppra oral solution (100 mg/mL) is the preferred form of administration for children under 6 years old, for children and adolescents (6-17 years old) who weigh less than 50 kg, and when it is difficult to administer an accurate dose with tablets.
Crushing/halving/chewing
Do not chew. The tablet is intended to be swallowed. No information is available regarding crushing/pulverizing the tablet. The tablet may be halved in order to facilitate swallowing, but not in order to divide it into equal parts. Once the tablet is halved, both its halves should be swallowed together immediately.
Duration of treatment
- Keppra is used as a chronic treatment. Treatment with Keppra should be continued as long as your doctor tells you to continue with it.
- Do not discontinue the treatment without an instruction from the doctor, since discontinuing the treatment in this way may increase your seizures.

If you took an overdose or a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital and take the package of the medicine with you. The possible side effects in case of an overdose are: drowsiness, irritability, aggressiveness, impaired alertness, breathing suppression and death.
If you have forgotten to take this medicine at the required time, do not take a double dose.
Contact the doctor for directions.
Follow the treatment as recommended by the doctor.
If you stop taking the medicine:
When discontinuing the treatment, Keppra should be stopped gradually in order to prevent an increase in seizures.
If the doctor decides to stop the treatment with Keppra, he will instruct you how to reduce the use gradually.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Keppra may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Contact the doctor or the nearest emergency room immediately if you experience:
- Weakness, dizziness or difficulty breathing. These may be the signs of a severe allergic (anaphylactic) reaction.
- Swelling of the face, lips, tongue and throat (Quincke's oedema).
- Flu-like symptoms and facial rash accompanied by disseminated rash with high fever, high levels of liver enzymes and one type of white blood cells (eosinophils) in blood tests, and enlarged lymph nodes (DRESS syndrome).
- Decrease in urine volume, fatigue, nausea, vomiting, confusion and swelling of the legs, ankles and feet. These may be signs of a sudden decrease in renal function.
- A skin rash which may form blisters and look like small targets (dark spots surrounded by a lighter area, surrounded by a darker-shade ring) (erythema multiforme).
- A disseminated rash with blisters and skin peeling, especially around the mouth, nose, eyes and genitalia (Stevens-Johnson syndrome).
- A more severe rash which causes skin peeling in more than 30% of body surface area (toxic epidermal necrolysis).
- Signs of severe mental changes or if anyone around you observes signs of confusion, sleepiness, memory loss (amnesia), memory impairment (forgetfulness), abnormal behavior or other neurological signs which include involuntary or uncontrolled movements. These may be symptoms of encephalopathy.

The most common side effects are nasopharyngitis, drowsiness, tiredness and dizziness.
Side effects such as sleepiness, fatigue and dizziness may appear more frequently in the beginning of the treatment or when the dosage is increased. These effects usually subside with time.
Very common side effects - side effects that occur in more than one out of ten users:
- Nasopharyngitis.
- Drowsiness, headache.

Common side effects - side effects that occur in 1-10 out of 100 users:
- Loss of appetite (anorexia).
- Depression, hostility or aggressiveness, anxiety, insomnia, irritability or restlessness.
- Spasms, balance disturbances, dizziness, lethargy (a state of lack of energy and lack of enthusiasm), tremor.
- Vertigo (sensation of giddiness).
- Cough.
- Abdominal pain, diarrhea, indigestion, vomiting, nausea.
- Rash.
- Weakness and tiredness.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
- Decreased number of blood platelets, decreased number of white blood cells.
- Decrease or increase in weight.
- Suicide attempts and suicidal thoughts, mental disorder, abnormal behavior, hallucinations, anger, confusion, panic attack, mental imbalance/mood swings, agitation.
- Memory loss, memory impairment (amnesia), impaired coordination/lack of muscle control (ataxia), numbness (paresthesia), lack of concentration.
- Double vision, blurred vision.
- Abnormal results/increase in liver function test.
- Hair loss, eczema, skin itching.
- Muscle pains, muscle weakness.
- Proneness to injuries.

Rare side effects - side effects that occur in 1-10 out of 10,000 users:
- Infection.
- Decreased number of all types of blood cells.
- Severe allergic reactions (DRESS, anaphylactic reaction [a severe allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat]).
- A decrease in blood sodium concentration.
- Suicide, personality disorders, thinking disturbances (slow thinking, inability to concentrate).
- Delirium
- Encephalopathy (see subsection "Contact the doctor or the nearest emergency room immediately if you experience" for detailed description of the symptoms).
- Uncontrollable muscle spasms, which affect the head, torso and limbs, difficulty in controlling movement, excessive movements (hyperkinesia).
- Inflammation of the pancreas (pancreatitis).
- Liver failure, inflammation of the liver (hepatitis).
- Sudden decrease in renal function.
- Skin rash (erythema multiforme) which may manifest as small target-like blisters (dark dots in the middle, surrounded by a lighter area, surrounded by a darker-shade ring), disseminated rash with blisters and skin peeling, especially around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), or a more severe form that causes peeling of more than 30% of skin surface area (toxic epidermal necrolysis).
- Rhabdomyolysis (muscle tissue breakdown) and rise in creatine phosphokinase blood levels. This effect is more common in Japanese than non-Japanese patients.
- Limping or difficulty walking.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.
Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:
https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (Exp.) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature lower than 25°C. Store in the original package.

6. Additional information:

- In addition to the active ingredient the medicine also contains:
  Keppra 250 mg contains:
  Sodium Croscarmellose, Opadry 85F20694 , Colloidal anhydrous silica, Macrogol 6000, Magnesium stearate
  Keppra 500 mg contains:
  Sodium Croscarmellose, Opadry 85F32004, Colloidal anhydrous silica, Macrogol 6000, Magnesium stearate
  Keppra 1000 mg contains:
  Sodium Croscarmellose, Opadry 85F18422, Colloidal anhydrous silica, Macrogol 6000, Magnesium stearate
- What does the medicine look like and what are the contents of the package:
  Keppra 250 mg tablets: a blue, oblong, film-coated tablet, scored on one side. Debossed with "ucb" on one side of the score line and "250" on the other side of the score line.
  Keppra 500 mg tablets: a yellow, oblong, film-coated tablet, scored on one side. Debossed with "ucb" on one side of the score line and "500" on the other side of the score line.
  Keppra 1000 mg tablets: a white, oblong, film-coated tablet, scored on one side. Debossed with "ucb" on one side of the score line and "1000" on the other side of the score line.
  The tablets are packed in aluminum blisters, 10 tablets per blister. In a carton package. In different sizes. Not all package sizes may be marketed.
- **License holder/importer and the address:** CTS Ltd., 4 Haharash St., Hod Hasharon.
- **Name and address of the manufacturer:** UCB Pharma S.A., BELGIUM. Allee De La Recherche 60, Bruxelles, Belgium
- This leaflet was reviewed and approved by the Ministry of Health in 03/2016 and has been updated in accordance with the Ministry of Health instructions in 01/2020.
- Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Keppra 250 mg	132-64-31181
Keppra 500 mg	132-65-31182
Keppra 1000 mg	132-66-31183