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

The medicine is dispensed with a doctor's prescription only

Keppra oral solution 100 mg/ml

The active ingredient and its concentration:
Levetiracetam 100 mg/1 ml
For a list of inactive ingredients and allergens in the preparation – 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 you. 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 for different types of epilepsy in adults over the age of 16.
2. As adjunctive therapy to other anti-epileptic medicines in:

- Adult and children patients from 4 years of age with certain types of epilepsy.
- Adult and adolescent patients from 12 years of age with juvenile myoclonic epilepsy or idiopathic generalised 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.
- You observed slower growth or unexpected puberty in your child, refer to 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 valuable possessions.

- You or anyone in your family has a history of irregular heart rate (according to an ECG test) or if you have a medical condition or you are taking medicines that can cause irregular heart rate or disturbances in salt balance.
- 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.
  - Epilepsy worsening: rarely, you may experience increased frequency or worsening of the seizures, particularly during the first month following the beginning of treatment or dosage increase. If during treatment the frequency of the seizures increases (e.g., more seizures) or if they worsen, refer to the attending doctor as soon as possible.
    In a very rare form of early-onset epilepsy (epilepsy associated with SCN8A mutations) that causes multiple types of seizures and impairs skills, the seizures may persist or worsen during the treatment.

In case one or more of these signs or any other alarming behavioral pattern appears – refer to the doctor immediately!
Children and adolescents
Keppra is not intended to be a monotherapy for children and adolescents under the age of 16.
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 an hour 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 the combined therapy and termination of the combined therapy should be considered as necessary.

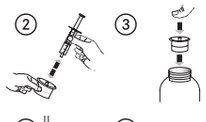
Use of the medicine and food
The medicine can be diluted in a glass of water. The medicine may be taken with or without food. After taking this medicine, you may feel a bitter taste.
Use of the medicine and alcohol consumption
No information is available regarding an interaction between alcohol and this 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. There are two studies that do not indicate an increased risk of autism or intellectual disability in children of mothers who have taken levetiracetam during pregnancy. Nevertheless, the available information on the effect of levetiracetam on neural development in children is limited.
Breastfeeding is not recommended during treatment with Keppra.
Driving and operating machinery
Keppra may impair your ability to drive or operate dangerous 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 dangerous machinery until you feel fit to perform these actions.
Children should be cautioned against riding a bicycle or playing near a road etc.
Important information regarding some of the ingredients of the medicine
Keppra solution contains methyl paraben and propyl paraben, which may cause an allergic reaction (it may appear after the medicine has been used for some time).
Keppra solution contains maltitol. If you have been told that you are suffering from sensitivity to certain types of sugars, you should refer to the doctor before taking this medicine.
The medicine contains less than 23 mg of sodium per 1 ml, and is therefore considered sodium-free.

3. How should you use the medicine?

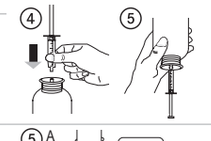
Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined by the doctor only.
The generally accepted dosage is:
Monotherapy in adults and adolescents over the age of 16:
The recommended starting dosage is 250 mg (2.5 ml) twice daily, which should be increased to an initial therapeutic dosage of 500 mg (5 ml) twice daily after two weeks. The dosage can be increased by 250 mg (2.5 ml) twice daily every two weeks, depending on the clinical response. The maximum dosage is 1500 mg (15 ml) twice daily.
Adjunctive therapy for adults (18 years and above) and adolescents (12 to 17 years) weighing 50 kg or more:
The initial therapeutic dosage is 500 mg (5 ml) twice daily. This dosage can be started on the first day of treatment.
Depending on the clinical response and tolerance, the daily dosage can be increased up to 1500 mg (15 ml) twice daily. The dosage can be increased or decreased by increments of 500 mg (5 ml) twice daily, every 2-4 weeks.
Special populations:
The elderly, patients with impaired kidney/liver function: dosage adjustment will be done by the attending doctor.
Children: the doctor will determine the form of administration according to the age, weight and dosage.
Do not exceed the recommended dose.
Method of administration
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.
After measuring the required dosage with the measuring syringe, the solution may be diluted in a glass of water, and you may drink it with or without food.
Instructions on how to use the syringe:

1.
Open the bottle: press the cap and turn it counterclockwise (figure no. 1).

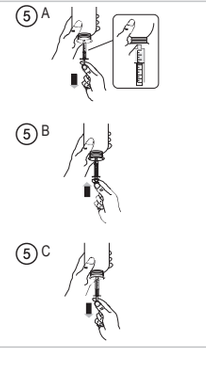
2.
Follow these steps the first time you use Keppra:
- Separate the adaptor from the syringe (figure no. 2).
- Insert the adaptor into the bottle's neck (figure no. 3). Make sure the adaptor is properly set. There is no need to remove the adaptor after use.



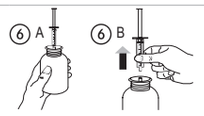
3.
A. Follow these steps each time you take Keppra:
- Connect the syringe to the opening in the adaptor (figure no. 4).
- Turn the bottle upside-down (figure no. 5).



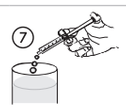
B.
- Hold the bottle upside-down in one hand and use the other hand to fill the syringe.
- Fill the syringe with a small amount of solution by pulling the piston downwards (figure no. 5A).
- Afterwards, push the piston up to remove air bubbles (figure no. 5B).
- Pull the piston downwards all the way to the marking in ml of the dose prescribed by the doctor (figure no. 5C).
- The piston may rise back up on the first dose. Therefore, ensure that the piston is kept in position until the syringe is disconnected from the bottle.



C.
Turn the bottle the right way up (figure no. 6A). Separate the syringe and the adaptor (figure no. 6B).



D.
Empty the syringe's contents into a glass of water by pressing on the piston all the way to the end of the syringe (figure no. 7).



E.
- Drink the entire glass of water.
- Close the bottle with the plastic cap (there is no need to remove the adaptor).
- To clean the syringe, rinse with cold water only, while moving the piston several times up and down to fill and empty the water, without separating the two components (figure no. 8).
- Keep the bottle, the syringe and the leaflet inside the carton package.

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 to a hospital emergency room and take the package of the medicine with you. The possible side effects in case of an overdose are: drowsiness, irritability, aggressiveness, reduced alertness, breathing suppression and coma.
If you have forgotten to take this medicine at the required time, do not take a double dose. Refer to 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 (for example, in adults and adolescents weighing more than 50 kg: reducing the dosage by 500 mg twice daily every 2-4 weeks; in children and adolescents weighing less than 50 kg: dosage reduction should not exceed 10 mg/kg twice daily every two weeks) 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 a 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.
Refer to 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 a type of white blood cells (eosinophils) in blood tests, enlarged lymph nodes and the involvement of other body organs (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 dark ring) (erythema multiforme).
- A disseminated rash with blisters and skin peeling, especially around the mouth, nose, eyes and genitals (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, drowsiness, 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, fatigue and dizziness.
Side effects such as drowsiness, 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 – effects that occur in more than one out of ten users:

- Nasopharyngitis.
- Drowsiness, headache.

Common side effects – effects that occur in 1-10 out of 100 users:

- Lack 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 spinning).
- Cough.
- Abdominal pain, diarrhea, indigestion, vomiting, nausea.
- Rash.
- Weakness and fatigue.

Uncommon side effects – 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 – 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 "Refer to the doctor or the nearest emergency room immediately if you experience" for a detailed description of the symptoms).
- Increased frequency or worsening of the seizures.
- Uncontrollable muscle spasms, which affect the head, torso and limbs, difficulty in controlling movement, excessive movements (hyperkinesia).
- Altered heart rate (ECG).
- 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 spots in the middle, surrounded by a lighter area, surrounded by a dark 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.
- A combination of fever, muscle stiffness, unstable blood pressure and heart rate, confusion, decreased level of consciousness (possible signs of a disorder called malignant neuroleptic syndrome). This effect is more common in Japanese than non-Japanese patients.

Very rare side effects – effects that occur in less than one out of 10,000 users:

- Repetitive and uncontrollable thoughts or sensations or an urge to do something over and over again (obsessive compulsive disorder).

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 in the original package in order to protect from light at a temperature below 25°C.
- Once the bottle is opened for the first time, the solution may be used for 7 months.

6. Additional information:

- In addition to the active ingredient the medicine also contains:
  Purified water, Maltitol liquid, Glycerol 85%, Acesulfame potassium, Methyl paraben, Ammonium glycyrrhizate, Sodium citrate, Propyl paraben, Grape flavour, Citric acid monohydrate.
- What does the medicine look like and what are the contents of the package?
  A glass bottle containing 300 ml of clear liquid. The package includes a measuring syringe and an adaptor between the bottle and the syringe.
- License holder and the address: CTS Ltd., 4 Haharash St., Hod Hasharon.
- Name and address of the manufacturer: UCB S.A., BELGIUM. Allee De La Recherche 60, Bruxelles, Belgium
- This leaflet was revised in 11/2025 in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 139-50-31500-00