



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EMA recommends measures to ensure safe use of Keppra oral solution

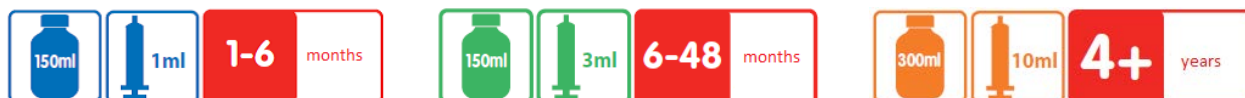
Medicine should only be used with dosing syringe included in the package

Several measures have been put in place to ensure that the correct dosing syringe is used to measure Keppra oral solution, and thus avoid medication errors. Keppra (levetiracetam) is a medicine used to treat epilepsy in adults and children.

In children, the dose of Keppra depends on the child's bodyweight and age, and the oral solution is the preferred formulation for use in children less than 6 years of age. The medicine is available as a 100 mg/ml solution in either a 150 or 300 ml size bottle, and it comes with a 1, 3 or 10 ml syringe.

Cases of accidental overdose have been reported with levetiracetam oral solution; the majority of cases occurred in children aged between 6 months and 11 years. Most of the cases occurred when the medicine was used with a wrong dosing syringe (e.g. a 10 ml syringe was used instead of a 1 ml one, leading to a 10-fold overdose), or because of a misunderstanding of the caregiver about how to properly measure the dose. Levetiracetam overdose often has no symptoms, but it may cause sleepiness, agitation, difficulty breathing and coma.

To avoid medication errors and the risk of overdose, parents and carers are advised that only the syringe provided with the package should be used to measure the dose of Keppra. The different medicine's cartons and labels will be coloured differently and clearly indicate the volume of the bottle, the volume of the dosing syringe, and the age range of the child that the medicine should be used for:



The package leaflet will also include clearer instructions for parents and carers in order to minimise the risk of using an incorrect dose. Parents and carers are advised always to discard the syringe once the medicine's bottle is empty.

### Information for parents and carers

- Keppra is a medicine used to treat epilepsy in adults and children. It contains the active substance levetiracetam.



- The preferred formulation of Keppra for use in children less than 6 years of age is an oral solution to be given by mouth, using the dosing syringe included in the medicine's package. Depending on the age of the child, this can be a 1, 3 or 10 ml syringe.
- There have been cases where the wrong dosing syringe was used to measure the dose of the oral solution (e.g. a 10 ml syringe was used instead of a 1 ml one), or the dose was not measured properly, resulting in patients taking a higher dose of the medicine. In some cases, overdose can cause sleepiness, agitation, difficulty breathing and coma.
- The carton and label on the bottle of Keppra oral solution will clearly indicate using different colours the volume of the bottle, the volume of the dosing syringe, and the age range for whom the medicine is intended.
- Parents and carers will be advised by their doctor or pharmacist on how to measure the correct dose of Keppra.
- When measuring the dose of Keppra oral solution, parents and carers should use only the dosing syringe included in the package. Once the bottle is empty, the syringe should be thrown away and not kept.
- Parents and carers who have any concerns about the medicine should speak to their doctor or pharmacist.

### **Information for healthcare professionals**

Cases of an up to 10-fold accidental overdose with levetiracetam oral solution have been reported, with the majority of cases occurring in children aged between 6 months and 11 years. In the cases where the cause of the reported accidental overdosing could be retrieved, it was either due to the use of an inappropriate syringe or the misunderstanding of the caregiver about how to properly measure the dose.

The outer packaging and bottle labels of Keppra 100 mg/ml oral solution will use colours to better differentiate each presentation: (i) blue for the 150 ml bottle with 1 ml syringe; (ii) green for the 150 ml bottle with 3 ml syringe; (iii) orange for the 300 ml bottle with 10 ml syringe.

Healthcare professionals should follow these recommendations:

- Doctors should ensure that the age-appropriate presentation of Keppra is prescribed.
- Doctors should always prescribe the dose in mg with ml equivalence based on the correct age of the patient.
- Pharmacists should ensure that the appropriate presentation of Keppra is dispensed.
- With every prescription, healthcare professionals should advise the patient and/or caregiver on how to measure the prescribed dose.
- With every prescription, healthcare professionals should remind patients or caregivers to use only the syringe included in the medicine's package. Once the bottle is empty, the syringe should be discarded.

## **More about the medicine**

Keppra (levetiracetam) is a medicine for the treatment of epilepsy. It can be used on its own in patients from 16 years of age with newly diagnosed epilepsy, to treat partial-onset seizures with or without secondary generalisation. It can also be used as an add-on to other anti-epileptic medicines to treat partial-onset seizures with or without generalisation in patients from one month of age; myoclonic seizures in patients from 12 years of age with juvenile myoclonic epilepsy; primary generalised tonic-clonic seizures in patients from 12 years of age with idiopathic generalised epilepsy.

Keppra is available as an oral solution, as tablets and as a solution for infusion (drip) into a vein. More information on Keppra can be found on the Agency's website: [ema.europa.eu/Find\\_medicine](http://ema.europa.eu/Find_medicine).

Several generics of Keppra are marketed in the European Union. Companies that market generic levetiracetam oral solutions are also expected to use colours to differentiate one presentation from another, and to clearly indicate on the package and the label the age range of the child that the presentation should be used for, and which dosing device should be used.

## **More about the procedure**

The cases of overdose with levetiracetam oral solution were reviewed in the context of a safety signal evaluation. A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation.

The review of this safety signal was carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines. The PRAC recommendations were sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which endorsed them. The company that markets Keppra is expected to take action according to the recommendations.

## **Contact our press officer**

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