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STN-2026-00991

30th June 2026

PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Levetiracetam (Keppra) Oral Solution (150 ml Bottle for Children Aged 6 Months To 4 Years): Risk of Medication Error Due To Change of Dosing Syringe

Dear Healthcare Professional,

UCB Pharma Ireland Limited in agreement with the European Medicines Agency and the Health Products Regulatory Authority would like to inform you of the following:

Summary

- **A new 5 mL dosing syringe delivering up to 500 mg of levetiracetam (Keppra) oral solution used in children aged 6 months to 4 years (150 mL bottle), will replace the 3 mL dosing syringe of levetiracetam, delivering up to 300 mg levetiracetam.**
- **When prescribing and dispensing levetiracetam (Keppra) oral solution with the new 5 mL syringe, inform caregivers about the change in the volume of the dosing syringe. Caregivers should be counselled on the correct dose and how to measure the correct dose with the 5 mL syringe. Caregivers should also be warned that the new 5 mL syringe has additional graduations of 0.25 mL compared to the 3 mL syringe.**
- **When dispensing levetiracetam (Keppra) oral solution (150 mL bottle), be aware that both the 3 mL syringe and new 5 mL syringe may be available at the same time until the old stock is exhausted. Specific attention should be given to the packaging where 'NEW SYRINGE' is printed in red to ensure caregivers are counselled appropriately.**
- **Advise caregivers to read the instructions in the Package Information Leaflet on how to recognize signs and symptoms of a levetiracetam overdose and what to do in this situation, as well as how to use and clean the syringe.**

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Background on the safety concern

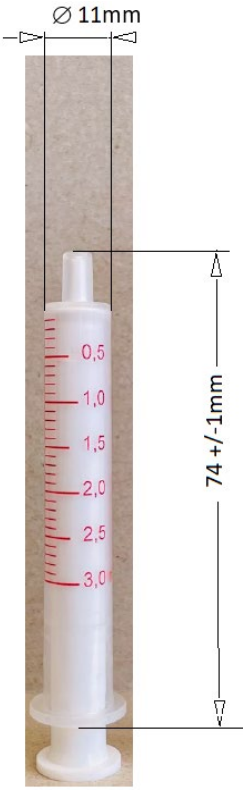
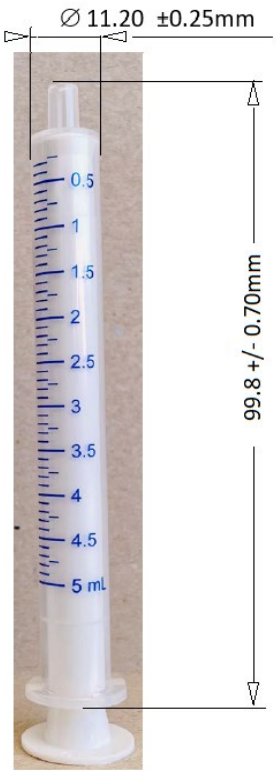
Levetiracetam (Keppra) is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy.

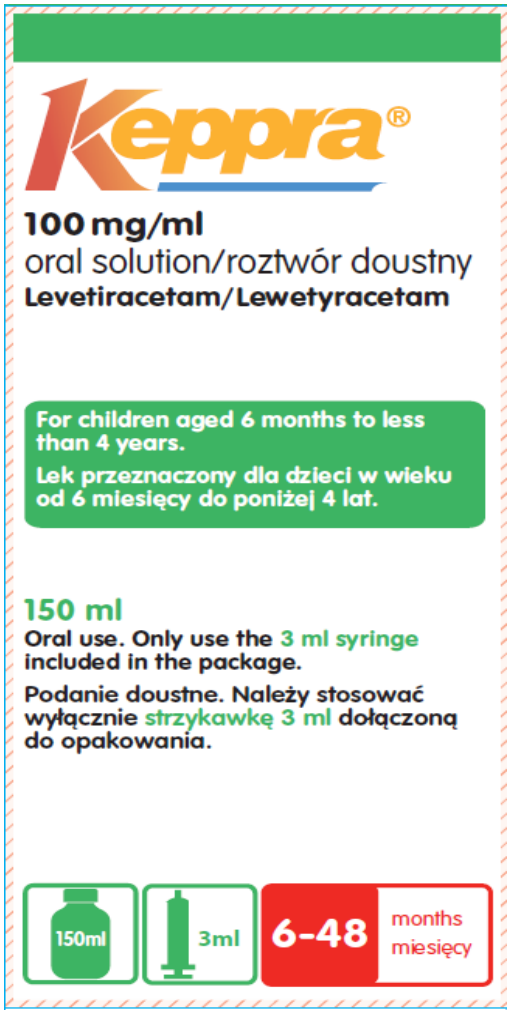
Levetiracetam (Keppra) is indicated as adjunctive therapy in the treatment of:

- partial onset seizures with or without secondary generalisation in adults, adolescents, children and infants from 1 month of age with epilepsy.
- 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.

One of the current presentations of levetiracetam (Keppra) 100 mg/mL oral solution in a 150 mL bottle includes a 3 mL dosing syringe and is intended for use in children aged 6 months to 4 years. The 3 mL dosing syringe (delivering up to 300 mg of levetiracetam) is being replaced with a 5 mL dosing syringe (delivering up to 500 mg levetiracetam). While the new 5 mL syringe is graduated every 0.1 mL, it also has additional graduations of 0.25 mL compared to the 3 mL syringe. Please see Table 1 below for more information.

Table 1: Differences between the 3 mL and 5 mL dosing syringe for patients aged 6 months to 4 years for levetiracetam (Keppra) oral solution (150 mL bottle)

	Old 3 mL dosing syringe	New 5 mL dosing syringe
Presentation		
Graduation markings	From 0.3 mL to 3 mL in 0.1 mL intervals	From 0.3 mL to 5 mL in 0.1 mL intervals and from 0.25 mL to 5 mL in 0.25 mL intervals.

	Old 3 mL dosing syringe	New 5 mL dosing syringe
Outer packaging		

The product information, including immediate and outer packaging, is being updated to reflect this change.

There is a potential risk of medication error due to the changes related to the dosing syringe for this presentation of levetiracetam (Keppra) oral solution. Overdose of levetiracetam (Keppra) due to medication error could result in somnolence, agitation, aggression, depressed level of consciousness, respiratory depression, and coma. Further information related to the management of overdose can be found in section 4.9 of the Summary of Product Characteristics.

When prescribing and dispensing levetiracetam (Keppra) oral solution with the new 5 mL dosing syringe for children aged 6 months to 4 years, caregivers should be informed about the change in the volume of the syringe and about the additional graduations of 0.25 mL on the new syringe. They should also be advised to read the updated instructions for using the new 5 mL syringe to measure the appropriate dose for the patient in the Package Leaflet.

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Caregivers should also be informed about the updated instructions in the Package Leaflet for cleaning the syringe. The syringe should be cleaned by rinsing it with cold water and moving the plunger several times up and down to take up and expel the water, without separating the 2 components.

There are no changes to the dosing syringes in the following presentations of levetiracetam (Keppra) oral solution:

- 150 mL bottle with 1 mL dosing syringe (for children aged 1 month to 6 months).
- 300 mL bottle with 10 mL dosing syringe (for children aged 4 years and older).

Warning: Healthcare professionals and caregivers should be aware that the dosing device supplied with levetiracetam (Keppra) oral solution for children aged 6 months to 4 years may differ from the dosing devices supplied with generic presentations of levetiracetam oral solution intended for a similar age group.

Call for reporting

Healthcare professionals should report any suspected adverse reactions, including medication errors via HPRA Pharmacovigilance. Website www.hpra.ie.

Company Contact Point

Should you have any questions, please contact UCB Pharma Ireland Ltd via UCBCares® on 1800 930075 (freephone) or by email UCBCares.IE@ucb.com.

Yours faithfully

Head Of Medical Affairs and Operations

UCB Pharma Ireland Limited