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LEVETIRACETAM (KEPPRA) ORAL SOLUTION (150ML BOTTLE FOR CHILDREN AGED 6 MONTHS TO 4 YEARS): RISK OF MEDICATION ERROR DUE TO CHANGE OF DOSING SYRINGE

Dear Healthcare Professional,

UCB Pharma Limited in agreement with the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- **A new 5mL dosing syringe delivering up to 500mg of levetiracetam (Keppra) oral solution used in children aged 6 months to 4 years (150mL bottle), will replace the 3mL dosing syringe of levetiracetam, delivering up to 300mg levetiracetam.**
- **When prescribing and dispensing levetiracetam (Keppra) oral solution with the new 5mL 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 5mL syringe. Caregivers should also be warned that the new 5mL syringe has additional graduations of 0.25mL compared to the 3mL syringe.**
- **When dispensing levetiracetam (Keppra) oral solution (150mL bottle), be aware that both the 3 mL syringe and new 5mL 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.**

Background on the safety concern

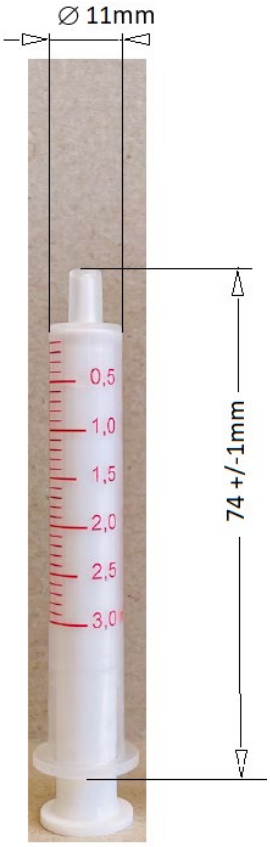
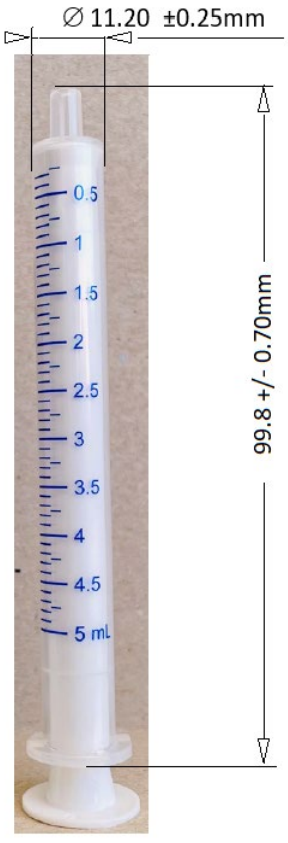
Levetiracetam (Keppra) is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy.

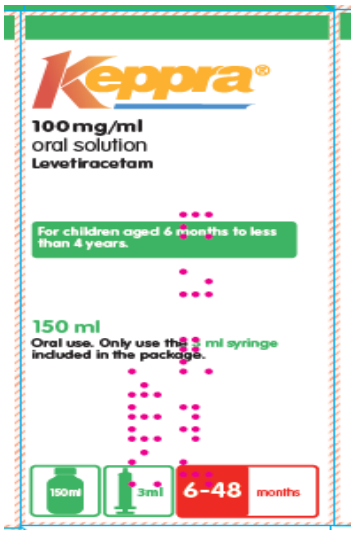
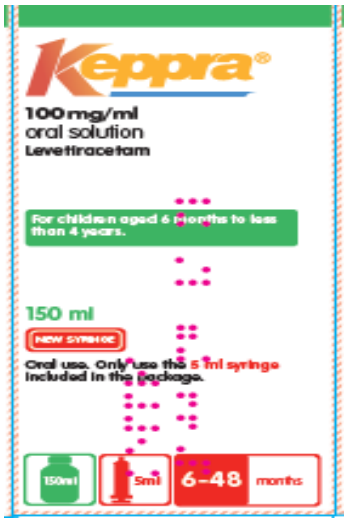
Levetiracetam (Keppra) is indicated as adjunctive therapy

- 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.
- in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy.
- in the treatment of 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) 100mg/mL oral solution in 150mL bottle includes a 3mL dosing syringe and is intended for use in children aged 6 months to 4 years. The 3mL dosing syringe (delivering up to 300mg of levetiracetam) is being replaced with a 5mL dosing syringe (delivering up to 500mg levetiracetam). While the new 5mL syringe is graduated every 0.1mL, it also has additional graduations of 0.25mL compared to the 3mL syringe. Please see Table 1 below for more information.

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

	Old 3mL dosing syringe	New 5mL dosing syringe
Presentation		

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

The product information, including immediate and outer packaging, are 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 the section 4.9 of the Summary of Product Characteristics.

When prescribing and dispensing levetiracetam (Keppra) oral solution with the new 5mL dosing syringe to 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 0.25mL on the new syringe. They should also be advised to read the updated instructions for using the new 5mL syringe to measure the appropriate dose for the patient in the Package Leaflet.

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:

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

Call for reporting

Healthcare professionals should report any suspected adverse reactions, including medication errors to the MHRA through the Yellow Card scheme that is available on the following:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Company Contact Point

Should you have any questions, please contact UCB Pharma Ltd via UCBCares® on 0800 279 3177 (freephone) or by email UCBCares.UK@ucb.com