UCB (Pharma) Ireland Limited
United Drug House, Magna Drive, Magna Business Park, Citywest Rd, Dublin 24

6th April 2010

Notification

Potential for dosing error when using Keppra® (levetiracetam) oral solution due to change in syringe graduation markings, and new presentations for infants and children younger than 4 years of age

Summary:

Caution should be taken in order to avoid potential dosing errors with Keppra® (levetiracetam) oral solution following:

(a) **The change in syringe graduation markings:** The graduation markings of the 10 ml syringe that is provided with the 300 ml bottle Keppra® oral solution presentation have changed from milligrams (mg) to millilitres (ml). It is important to consider this syringe modification to avoid dosing error when the 300 ml presentation is used for patients already treated with Keppra®.

(b) **The introduction of new oral solution presentations:** It is vital that the appropriate presentation is prescribed in relation to the age of the patient. The 300ml bottle Keppra® oral solution presentation is not recommended for patients younger than 4 years of age. Two new 150ml bottle presentations are available to ensure accurate dosing in:

- infants aged from 1 month to less than 6 months, and
- infants 6 months and older, and children 1 to 4 years of age.

Further information on the safety concern:

Keppra® has now been approved for use as adjunctive therapy in children with partial-onset seizures as young as 1 month of age. To facilitate more accurate dosing in young children, a smaller sized bottle (150 ml of Keppra® 100mg/ml) with a smaller sized syringe (either 1 ml or 3ml) graduated in millilitres has been made available.

To ensure consistency between the original (300 ml) Keppra® oral solution bottle and syringes, and the new 150 ml bottle and syringes, a new 10 ml syringe with a graduation every **0.25 ml** instead of every **25 mg** has been developed to be included with the 300ml bottle of Keppra® oral solution. With this change from mg-markings to ml-markings for the new 10 ml syringe, caution should be taken during administration to avoid any dosing errors, particularly in patients already treated with Keppra.

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Further information on recommendations to health care professionals:

Keppra® Oral solution (100 mg/ml) is now available in 3 different presentations. Age groups are also indicated on the outer carton of the package.

- 300 ml bottle with a 10 ml syringe, graduated every 0.25 ml, for children from 4 years of age, adolescents and adults;
- 150 ml bottle with a 3ml syringe, graduated every 0.1 ml, for infants 6 months and older and children 1 to 4 years of age;
- 150 ml bottle with a 1ml syringe, graduated every 0.05 ml, for infants aged 1 month to less than 6 months.

It is recommended that the physician should prescribe the most appropriate pharmaceutical form, presentation and strength according to the patient's weight and dose. Please refer to the prescribing information in your country for further information.

Calls for reporting:

In case of dosing errors and other adverse reaction reporting, please contact medical information on Tel: +44 1753 534655, Fax: +44 1753 536632, E-Mail: medicalinformationuk@ucb.com and/or contact the national spontaneous reporting system on the IMB website: http://www.imb.ie/EN/Safety--Quality/Online-Forms/Human-Medicine-Adverse-Drug-Reaction.aspx

Contact Information:

Should you have any queries please contact UCB (Pharma) Ireland Limited Tel: 01 463 7395, Fax: 01 463 7396

Yours sincerely,

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ANNEX:
Keppra® (levetiracetam) Summary of Product Characteristics (September 2009)