

19 June 2017

Dear Healthcare Professional

Title: Levetiracetam : Safety Instructions for oral solution use to minimize Risk Of Overdosing By Medication Errors

Key Messages

- Cases of accidental overdose have been reported globally with the use of levetiracetam oral solution. The majority of cases occurred in children aged between 6 months and 11 years. Most of the cases have involved use of an incorrect syringe, 10 ml instead of 1 ml, presumably because the manufacturer had multiple presentations with different syringe sizes, or because of a misunderstanding of the caregiver about how to properly measure the dose. overdose may occur when the medicine is measured/administered using the wrong dosing syringe or when parents and/or caregivers misunderstand how to properly measure the dose.
- MAH is alerting prescribers to ensure accurately prescribed dosing based on a child's body weight and age and to carefully explain to parents/caregivers how to measure the prescribed dose to ensure the safe use of levetiracetam.
- Levetiracetam oral solution is the preferred formulation to be used in children under the age of 6 years. Levetiracetam overdose may cause somnolence, agitation, depressed level of consciousness, respiratory depression or coma.
- The current available presentation of levetiracetam oral solution (100mg/ml) is a 300 ml bottle with a 10 ml oral syringe graduated every 0.25 ml (corresponding to 25 mg). Doses for infants and young children aged from 1 month to less than 4 years should be administered with smaller volume syringes as below (syringes not provided in the pack):

Infants aged 1 month to less than 6 months

1 ml syringe

Graduated syringe every 0.05 ml (corresponding to 5 mg)

Infants and young children aged from 6 months to 48 months

2 or 3 ml syringe

Graduated syringe every 0.1 ml (corresponding to 10 mg)

Action Being Taken by MAH

MAH issues this letter to inform all healthcare providers about the importance of clearly explaining the correct dosage to parents and/or caregivers guiding them on how to properly measure the prescribed dose with an appropriate size graduated syringe.

This letter is being sent to you after agreement with the Egyptian Pharmacovigilance Center in Egypt (EPVC).

Action required by Health Care Providers

- You should always prescribe the dose in mg with ml equivalence based on the correct age of the patient*.
- You are advised to educate patients and/or caregivers on how to measure the prescribed dose and to use the appropriately graduated syringe.
- You should share this information with relevant staff under your supervision.

**Please refer to the Country Product Information for full prescribing information.*

Further Information

On the 14 October 2016, the European Medicines Agency published a recommendation (EMA/668736/2016) related to measures to ensure safe use of (Levetiracetam) oral solution. To avoid medication errors and the risk of overdose either a 1ml or a 3 ml syringe should be used for the children below 4 years of age (depending on the age of the child).

Any adverse events with the use of levetiracetam should be reported to MAH using the usual channels.

Please share the information in this letter with relevant colleagues and health care personnel.