HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Levetiracetam 100mg/ml Oral Solution - Global reports of medication errors resulting in the administration of higher than intended doses of levetiracetam

The European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) recently completed a review of global reports of medication errors with levetiracetam oral solution, including case reports of an up to 10-fold accidental overdose. The majority of cases occurred in children aged between 6 months and 11 years and where information could be retrieved from reports, the use of an inadequate dosing device (e.g. confusion between a 1ml and a 10ml syringe) was identified as an important cause. Another identified cause was the misunderstanding of the caregiver about how to properly measure the dose.

In Ireland, levetiracetam is currently available in a number of different presentations, including tablets, solution for infusion and oral solution. The oral solution, authorised across the European Union since 2003, is approved for use, as monotherapy and adjunctive therapy in various forms of epilepsy in paediatric and adult patients.

Advice to Healthcare Professionals

- Physicians should always prescribe the dose in milligrams (mg) with millilitre (ml) equivalence based on the correct age.
- Physicians should prescribe the recommended presentation of levetiracetam oral solution with the appropriate syringe according to the age/bodyweight of the patient.
- Pharmacists should ensure the correct syringe is dispensed with the corresponding presentation:
  - 150ml bottle with 1ml syringe for infants from 1 month to less than 6 months;
  - 150ml bottle with 3ml syringe for children 6 months to less than 4 years and below 50kg bodyweight;
  - 300ml bottle with 10ml syringe for children 4 years and older and below 50kg bodyweight;
  - 300ml bottle with 10ml syringe for children, adolescents and adults with 50kg and more bodyweight.
- With each prescription, physicians and pharmacists should advise the patient/carer on how to measure the correct dose.
- Patients/carers should also be reminded frequently that only the syringe provided with the medicine should be used. Once the bottle is empty, the empty syringe should be discarded and not kept.
- The package leaflet and outer carton will be updated to improve clarity.
- The Marketing Authorisation Holder (MAH) for the brand Keppra circulated a Direct Healthcare Professional Communication (DHPC) (following approval by the HPRA) on this topic in November 2016.
- Healthcare professionals are reminded to report any medication errors associated with overdose to the HPRA Pharmacovigilance Department using the usual methods (www.hpra.ie).

Key Message

- Cases of an up to 10-fold accidental overdose with levetiracetam oral solution have been reported, the majority of which occurred in children aged between 6 months and 11 years.
- Doctors should always prescribe the dose in milligrams (mg) with millilitre (ml) equivalence based on the correct age.
- Pharmacists should ensure the appropriate presentation of the oral solution is dispensed.
- With every prescription and every dispensing, the doctor and pharmacist should advise the patient/caregiver on how to measure the prescribed dose.
- All suspected adverse reactions associated with levetiracetam oral solution should be reported to the HPRA via the various reporting methods available (www.hpra.ie)

Further information on levetiracetam-containing products including Keppra is available from www.hpra.ie and www.ema.europa.eu

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