Direct Healthcare Professional Communication

28 April 2017

Levetiracetam containing products 100 mg/mL oral solution presentations:

Risk of medication errors associated with overdose

Dear Healthcare Professional,

The generic medicine Marketing Authorisation Holders listed below, in agreement with the MHRA, would like to inform you of the following:

Summary

- Cases of an up to 10-fold accidental overdose with levetiracetam oral solution have been reported. The majority of cases occurred in children aged between 6 months and 11 years. The use of an inadequate dosing device (e.g. confusion between a 1 mL and a 10 mL syringe, resulting in a 10-fold overdose) was identified as an important cause
- Physicians should always prescribe the dose in mg with mL equivalence based on the correct age and bodyweight
- Pharmacists should ensure that the appropriate presentation of levetiracetam oral solution is dispensed
- With every prescription, physicians and pharmacists should advise the patient and/or caregiver on how to measure the prescribed dose
- With every prescription, physicians and pharmacists should remind patients or caregivers to use only the syringe delivered with the medicine. Once the bottle is empty the syringe should be discarded and not kept

Background on the safety concern

Levetiracetam overdose can lead to serious adverse events, like depressed level of consciousness, respiratory depression and coma.

In the cases where the cause of the reported accidental overdosing could be retrieved, it was either due to the use of an inappropriate syringe or the misunderstanding of the caregiver about how to properly measure the dose.

Physicians should prescribe the recommended presentation of levetiracetam oral solution with the appropriate syringe according to the age/bodyweight of the patient.

The pharmacist should ensure the right syringe is dispensed with the corresponding presentation:

- 150 mL bottle with 1 mL syringe for infants from 1 month to less than 6 months
- 150 mL bottle with 3 mL syringe for children 6 months to less than 4 years and below 50 kg bodyweight
- 300 mL bottle with 10 mL syringe for children 4 years and older and below 50 kg bodyweight
- 300 mL bottle with 10 mL syringe for children, adolescents and adults with 50 kg and more bodyweight

The Marketing Authorisation holders (MAH) listed will revise the patient information leaflet and outer packaging of their levetiracetam 100 mg/mL oral solution presentations to improve the clarity of the dose recommendations and to avoid confusion about the appropriate bottle size and syringe.

To further minimise the risk of dosing error, companies marketing more than one presentation of levetiracetam oral solution have been encouraged to use colour codes and pictograms to:

(i) differentiate one presentation from another
(ii) clearly state the age range for whom the presentation is intended (front warning on packaging and labelling)
(iii) clearly state on the packaging/labelling which dosing device should be used with a specific presentation

If you require additional information, please contact the medical information services of the individual company.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Please report:

- All suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- All suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

It is easiest and quickest to report ADRs online via the Yellow Cards website https://yellowcard.mhra.gov.uk/.

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