Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/40

Caution In Use

Issued 14 August 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Accord Healthcare Limited, UK

MEDICINE DETAILS

Levetiracetam Accord 100mg/ml oral solution

PL: 20075/0386

Active Ingredient: Levetiracetam

SNOMED code: 35241511000001104

GTIN: 05055565718797

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
E243884	31/08/2027	1 vial pack	Not Distributed
E244160	31/08/2027	1 vial pack	Not Distributed
E243885	31/08/2027	1 vial pack	16/01/2025
E244161	30/09/2027	1 vial pack	Not Distributed

Background

Accord Healthcare Limited, UK has informed the MHRA that the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SPC) do not contain all the required safety information.

The information missing in the various sections of the PIL and SPC is summarised in the Appendix of this notice.

The batches listed as 'not yet distributed' have also been manufactured with the incorrect PIL. The MHRA, in discussion with the Department of Health and Social Care, considers these products critical for patients, therefore these batches will be distributed without further repackaging. They are therefore included in the notification.

Advice for Healthcare Professionals:

The quality of the oral solution is not impacted as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals involved in the dispensing of these products should, where possible, signpost new patients on these medicines to the missing safety information. A summary of the missing safety information can be found in the Appendix of this notice. Upon request, Accord Healthcare Limited will provide hard copies of the updated PIL to pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information. To request hard copies of the PIL, please contact **0800 373573.**

Please follow the links to the correct documentation:

PIL: https://www.accord-healthcare-products.co.uk/document/pil-levetiracetam-accord-100mgml-oral-solution

SPC: https://www.accord-healthcare-products.co.uk/document/smpc-levetiracetam-accord-100mgml-oral-solution

Accord Healthcare Limited have confirmed that all future batches will contain the updated PIL.

Advice for Healthcare Professionals to Provide to Patients:

Patients should continue to take medicines as prescribed by their healthcare professional. The product quality of the impacted batches is not affected, however there is some missing safety information in the Patient Information Leaflet (PIL) that patients should be aware of. A summary of the missing safety information can be found in the Appendix of this notice.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Additional information:

For medical information enquiries please contact:

Accord Medical Information Department on **01271 385257**, email- medinfo@accord-healthcare.com.

For stock control enquiries please contact: Accord- Customer Services Team on **0800 373573**.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU

Telephone +44 (0)20 3080 6574

DMRC@mhra.gov.uk

Appendix :

PIL Section 1: What the medicine is and what it is used for

- Additional information:
  - Explanation of epilepsy and seizure types.
  - Clarified use in infants, children, and adolescents.

PIL Section 2: Before You Take

- Additional information:
  - Warning on pyrrolidone derivative allergy.
  - Macrogol interaction: avoid 1 hour before/after.
  - Clarified age restrictions for monotherapy (<16 years not recommended).
  - Clarified use in pregnancy

PIL Section 3: How to Take

- Additional information:
  - Bitter taste warning.
  - Detailed dosing for infants (1 month–6 months).

PIL Section 4: Possible Side Effects

- Additional information:
  - Symptoms of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Acute kidney injury (AKI), encephalopathy, Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis (SJS/TEN).
  - “Rhabdomyolysis” and increased Creatine phosphokinase (CPK).
  - “Limp or difficulty walking” as a possible adverse drug reaction (ADR).
  - Quincke’s oedema

PIL Section 6: Contents of the Pack

- Added: pH range “pH 5.0 to 7.0”.

SPC 4.2: Posology and method of administration

- Added:
  - bitter taste warning.
  - Clarified when oral solution formulation is applicable.

SPC 4.4: Special warnings and precautions for use

- Added:
  - Warning on acute kidney injury and advice on monitoring blood cell counts.

SPC 4.5: Interaction with other medicinal products and other forms of interaction

- Added:
  - interaction with methotrexate

SPC 4.6: Fertility, pregnancy and lactation

- Added:

- Information on use in women of child-bearing potential and post-marketing data on exposure in pregnant women.

SPC 4.7: Effects on ability to drive and use machines

- Clarified warning.

SPC 4.8: Undesirable effects

- Additional information:
  - Symptoms of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Acute kidney injury (AKI), encephalopathy, Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis (SJS/TEN).
  - “Rhabdomyolysis” and increased Creatine phosphokinase (CPK).
  - “Limp or difficulty walking” as a possible adverse drug reaction (ADR).
  - Quincke’s oedema

SPC 5.1: Pharmacodynamic properties

- Removed:
  - Difference in mechanism of action from other antiepileptics.
- Added:
  - Clinical trial data in infants under one year of age.