MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/40

Caution In Use

Issued 01 October 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Neuraxpharm UK Limited

MEDICINE DETAILS

Levetiracetam Neuraxpharm 250mg granules for oral solution in sachet

PL 49718/0073

Active Ingredient: levetiracetam

SNOMED code: 42426311000001104

GTIN: 5060673110623

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
2153678	09/2027	60	26/03/2026
2184895	02/2028	60	Not yet distributed.

MEDICINE DETAILS

Levetiracetam Neuraxpharm 500mg granules for oral solution in sachet

PL 49718/0074

Active Ingredient: levetiracetam

SNOMED code: 42426611000001109

GTIN: 5060673110630

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
2184908	02/2028	60	03/06/2026
2194807	04/2028	60	Not yet distributed.

MEDICINE DETAILS

Levetiracetam Neuraxpharm 750mg granules for oral solution in sachet

PL 49718/0075

Active Ingredient: levetiracetam

SNOMED code: 41543411000001107

GTIN: 5060673110647

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
2185161	02/2028	60	29/09/2025
2194917	04/2028	60	25/09/2025

MEDICINE DETAILS

Levetiracetam Neuraxpharm 1000mg granules for oral solution in sachet

PL 49718/0076

Active Ingredient: levetiracetam

SNOMED code: 42426811000001108

GTIN: 5060673110654

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
231350	01/2027	60	29/05/2024
2145725	05/2027	60	13/12/2024
2154064	10/2027	60	Not yet distributed.
2204270	04/2028	60	Not yet distributed.

MEDICINE DETAILS

Levetiracetam Neuraxpharm 1500mg granules for oral solution in sachet

PL 49718/0077

Active Ingredient: levetiracetam

SNOMED code: 41544811000001107

GTIN: 5060673110661

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
231175	01/2027	60	13/12/2024
231591	02/2027	60	19/08/2026
2248690	06/2029	60	Not yet distributed.

Background

Neuraxpharm UK Limited have informed the MHRA that a review of the approved Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) for Levetiracetam Neuraxpharm Granules for Oral Solution in Sachet has identified discrepancies between the current Neuraxpharm product safety information and the corresponding reference product information.

Currently all available stock is impacted. Following discussions between the MHRA and the Department of Health and Social Care, these products have been considered critical for patients who are unable to take tablet formulations and rely on this dosage form. Therefore, the affected batches will continue to be supplied without repackaging and are included in this notification.

A corrected version of the Patient Information Leaflet, containing the required information, is not yet available on the MHRA Products website. Neuraxpharm Limited have confirmed that all packs of Levetiracetam Neuraxpharm Granules for Oral Solution in Sachet distributed from June 2027 will contain an updated and correct PIL.

Advice for Healthcare Professionals:

Healthcare professionals are advised that the current Patient Information Leaflet (PIL) for Levetiracetam Neuraxpharm Granules for Oral Solution in Sachet does not contain all the information included in the corresponding reference product information.

1. **Healthcare professionals, including GPs, independent prescribers and specialist prescribers, involved in prescribing Levetiracetam should continue to prescribe and dispense Levetiracetam Neuraxpharm in accordance with the approved product information and manage patients according to their individual clinical circumstances.**

Healthcare Professionals should be informed:

- that the approved indication includes use in **infants from one month of age**.
- of the information relating to **very rare SCN8A mutation-associated early-onset epilepsy**.
- that there is evidence suggesting a **possible predisposition of the Japanese population to neuroleptic malignant syndrome (NMS)**.
- that **obsessive-compulsive disorder (OCD)** is a recognised **very rare adverse reaction**.
- that **multiorgan hypersensitivity reactions** is a recognised **rare adverse reaction**.

The following text has been included from other brands of levetiracetam products (reference product) that contain the correct information and indicate what sections will be updated in due course:

- SmPC section 4.4 and PIL section 2: *Lack of efficacy or seizure worsening has for example been reported in patients with epilepsy associated with sodium voltage-gated channel alpha subunit 8 (SCN8A) mutations.*
- SmPC section 4.8 and PIL section 4: *Evidence also suggests a possible predisposition of the Japanese population to neuroleptic malignant syndrome (NMS).*
- SmPC section 4.8 and PIL section 4: *Very rare cases of development of obsessive-compulsive disorders (OCD) in patients with underlying history of OCD or psychiatric disorders have been observed in post-marketing surveillance.*
- SmPC section 4.8: *Multiorgan hypersensitivity reactions. Multiorgan hypersensitivity reactions (also known as Drug Reaction with Eosinophilia and Systemic Symptoms, DRESS) have been reported rarely in patients treated with levetiracetam. Clinical manifestations may develop 2 to 8 weeks after starting treatment. These reactions are variable in expression, but typically present with fever, rash, facial oedema, lymphadenopathies, haematologic abnormalities and can be associated with the involvement of different organ systems, mostly the liver. If multiorgan hypersensitivity reaction is suspected, levetiracetam should be discontinued.*
- The reference product PIL section 1 includes the indication:

partial onset seizures with or without generalisation in adults, adolescents, children and infants from one month of age.
By comparison, the PIL for Levetiracetam Neuraxpharm currently states only: *partial onset seizures with or without generalisation in adults, adolescents and children.*

2. **Healthcare professionals involved in dispensing the impacted products, including pharmacy teams are advised to review the information contained within this notification and take this into account when dispensing this product.**
    a. **Where possible, patients should be provided a copy of the supplementary letter detailing the missing information from the PIL with each subsequent dispensing activity. A copy of the supplementary letter can also be found by scanning the below QR code.**
    b. **There is no expectation that patients should be contacted retrospectively, however if patients present with specific symptoms they should be referred to the appropriate healthcare professional.**

Additionally, Neuraxpharm Limited will provide a copy of the supplementary letter with each future delivery so that this can be provided to patients directly when the product is dispensed. To request hard copies of the supplementary letter, please contact Medinfo-uk@neuraxpharm.com, or telephone +44 (0) 330 128 0919 with your details, i.e. name, address, required number of supplementary letters.

Advice for Patients:

Patients should continue to take medicines from these batches as prescribed by your healthcare professional. The quality of the granules for oral solution in sachets is not affected by this issue.

Patients should contact the relevant healthcare professional if:

Patients should seek medical advice if they experience any unexpected change or worsening in their condition, including an increase in the frequency or severity of seizures.

Very rarely, changes in thoughts or behaviour, including new or worsening obsessive thoughts or repetitive behaviours, may occur. Patients should speak to their healthcare professional if they experience such symptoms.

Patients should seek urgent medical attention if they develop any combination of high temperature, marked muscle stiffness, confusion, reduced consciousness, or changes in blood pressure or heart rate, as these may be signs of a serious reaction known as neuroleptic malignant syndrome.

Patients should also seek urgent medical attention if they develop any combination of fever, skin rash, swelling of the face, swollen lymph nodes, or other unexplained symptoms affecting different parts of the body, particularly within 2 to 8 weeks of starting treatment, as these may indicate a serious hypersensitivity reaction known as DRESS.

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 all medical information enquiries and information on this product, please email Medinfo-uk@neuraxpharm.com, or telephone +44 (0) 330 128 0919.

For stock control enquiries please email info-uk@neuraxpharm.com, or telephone +44 (0) 118 211 4039.

Recipients of this Medicines Notification 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

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