

Supplementary Letter to the Patient Information Leaflet for Levetiracetam Granules for Oral Solution in Sachet

Levetiracetam Neuraxpharm 250mg granules for oral solution in sachet	PL 49718/0073
Levetiracetam Neuraxpharm 500mg granules for oral solution in sachet	PL 49718/0074
Levetiracetam Neuraxpharm 750mg granules for oral solution in sachet	PL 49718/0075
Levetiracetam Neuraxpharm 1000mg granules for oral solution in sachet	PL 49718/0076
Levetiracetam Neuraxpharm 1500mg granules for oral solution in sachet	PL 49718/0077

Dear Patient,

The approved Patient Information Leaflet (PIL) for the above products is missing important safety information. This issue impacts all batches, therefore Neuraxpharm UK Limited, as the marketing authorisation holder, are providing further information to make you aware of the missing information.

- **PIL Section 1 What Levetiracetam is and what it is used for:** partial onset seizures with or without generalisation in adults, adolescents, children and infants from one month of age.
- **PIL Section 2 What you need to know before you take Levetiracetam:** Aggravation of epilepsy: Your seizures may rarely become worse or happen more often, mainly during the first month after the start of the treatment or increase of the dose. In a very rare form of early-onset epilepsy (epilepsy associated with SCN8A mutations) that causes multiple types of seizures and loss of skills you may notice that the seizures remain present or are becoming worse during your treatment. If you experience any of these new symptoms while taking Levetiracetam Neuraxpharm, see a doctor as soon as possible.
- **PIL Section 4 Possible Side Effects:** Severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat]).
- **PIL Section 4 Possible Side Effects:** Evidence also suggests a possible predisposition of the Japanese population to neuroleptic malignant syndrome (NMS).
- **PIL Section 4 Possible Side Effects:** Very rare: may affect up to 1 in 10000 people • repeated unwanted thoughts or sensations or the urge to do something over and over again (Obsessive Compulsive Disorder).

Patients should continue to take medicines 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](#).