

IMPORTANT SAFETY INFORMATION

Lacosamide Neuraxpharm 10 mg/ml syrup (PL 49718/0079): Important safety information missing from current approved Summary of Product Characteristics regarding myoclonic seizures, ataxia and reproductive health counselling

Dear Healthcare Professional,

Neuraxpharm UK Ltd. in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA), would like to inform you of important safety information concerning **lacosamide**, including information missing from the current approved Summary of Product Characteristics (SmPC) for Lacosamide Neuraxpharm 10 mg/ml syrup.

Summary

- Lacosamide Neuraxpharm is indicated as a monotherapy in the treatment of partial-onset seizures with or without secondary generalization in adults, adolescents, and children from 4 years of age with epilepsy.
- Lacosamide Neuraxpharm is indicated as adjunctive therapy
 - In treatment of partial-onset seizures with or without secondary generalization in adults, adolescents and children from 4 years of age with epilepsy.
 - In the treatment of primary generalized tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalized epilepsy.
- **Myoclonic seizures and ataxia are recognised common adverse reactions to lacosamide** and are not currently included in the product information for Lacosamide Neuraxpharm 10 mg/ml syrup.
- Healthcare professionals should consider lacosamide as a potential cause of **new or worsening myoclonic seizures, impaired coordination, gait disturbance, or balance difficulties**.
- Physicians should discuss **family planning and contraception with women of childbearing potential** taking lacosamide.
- If a woman taking lacosamide **decides to become pregnant, treatment should be carefully re-evaluated**.

<https://bnf.nice.org.uk/drugs/lacosamide/>

Background on safety information

The current product information in SmPC for Lacosamide Neuraxpharm 10mg/ml syrup does not fully reflect the available safety information regarding the neurological adverse reaction profile and reproductive health counselling associated with lacosamide.

Myoclonic seizures and ataxia

The reference product information identifies **myoclonic seizures** and **ataxia** as adverse reactions to lacosamide, both classified as **common**.

These adverse reactions are not currently communicated elsewhere in the product information for Lacosamide Neuraxpharm 10 mg/ml syrup.

Healthcare professionals should therefore be aware:

- New or worsening **myoclonic seizures** may be treatment related and should not necessarily be interpreted solely as progression of the underlying epilepsy or inadequate seizure control.

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- **Ataxia**, including impaired coordination, gait disturbance or balance difficulties, may be treatment related and may affect mobility and functional status.

Awareness of these recognised adverse reactions is important when assessing patients receiving lacosamide and when assessing treatment response and considering whether treatment adjustment is appropriate.

The product information will be updated to include **myoclonic seizures** and **ataxia** as recognised adverse reactions, classified as **common**.

Women of childbearing potential

The reference product information includes specific advice concerning women of childbearing potential receiving lacosamide.

Physicians should discuss **family planning and contraception** with women of childbearing potential taking lacosamide.

If a woman decides to become pregnant, the use of lacosamide should be **carefully re-evaluated**.

The current product information contains guidance on lacosamide use during pregnancy. However, it does not fully address proactive family planning and treatment reassessment **before pregnancy occurs**.

The product information will therefore be updated to include this information.

Existing cautions and warnings

Healthcare professionals are reminded to consider the **existing cautions and warnings associated with lacosamide** when prescribing and managing patients receiving lacosamide.

Further information regarding lacosamide, including relevant cautions and warnings, is available in the [British National Formulary \(BNF\)](#).

Healthcare professionals should also refer to the current product information for Lacosamide Neuraxpharm 10 mg/ml syrup when prescribing and managing patients.

Further information on the use of antiepileptic medicines during pregnancy is also available in the *Drug Safety Update* article, [Antiepileptic drugs in pregnancy: updated advice following comprehensive safety review - GOV.UK](#)

Changes to the product information

The product information for Lacosamide Neuraxpharm 10 mg/ml syrup will be updated to ensure complete and consistent communication of the recognised safety profile of lacosamide.

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.

You can report via:

- the [Yellow Card website](#).
- the free Yellow Card app available from the Apple App Store or Google Play Store.
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing of onset, treatment dates, and product brand name.

Company contact point

If you require further information regarding this communication, please contact:

Neuraxpharm UK Ltd.

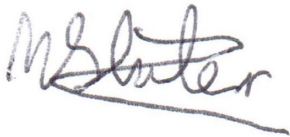
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Yours sincerely,



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