30 March 2023
EMA/CHMP/126756/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lacosamide Adroiq

lacosamide

On 30 March 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lacosamide Adroiq, intended for the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy. The applicant for this medicinal product is Extrovis EU Ltd.

Lacosamide Adroiq will be available as a 10 mg/ml solution for infusion. The active substance of Lacosamide Adroiq is lacosamide, an antiepileptic (ATC code: N03AX18) which selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilisation of hyper-excitable neuronal membranes.

Lacosamide Adroiq is a generic of Vimpat, which has been authorised in the EU since 29 August 2008. Since Lacosamide Adroiq is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Vimpat was not required. A question and answer document on generic medicines can be found here.

The full indication is:

> Lacosamide Adroiq is indicated as monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.
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> Lacosamide Adroiq is indicated as adjunctive therapy
>
> - in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.
> - in the treatment of primary generalised tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalised epilepsy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.