20 July 2017
EMA/CHMP/370634/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lacosamide Accord

lacosamide

On 20 July 2017, 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 Accord, intended for the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy. The applicant for this medicinal product is Accord Healthcare Ltd.

Lacosamide Accord will be available as 50 mg, 100 mg, 150 mg and 200 mg film-coated tablets. The active substance of Lacosamide Accord 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 Accord is a generic of Vimpat, which has been authorised in the EU since 29 August 2008. No bioequivalence studies have been conducted since a BCS-based biowaiver was granted,[2] in which assumption of equivalence in *in vivo* performance was justified by *in vitro* data. A question and answer document on generic medicines can be found here.

The approved indication is: "Lacosamide Accord is indicated as monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy." It is proposed that Lacosamide Accord is prescribed by physicians experienced in the treatment of 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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[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
[2] In accordance with Appendix III of the Guideline on investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/ Corr **)

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