27 June 2019
EMA/CHMP/343641/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lacosamide UCB

lacosamide

On 27 June 2019, 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 UCB, intended for the treatment of partial-onset seizures with or without secondary generalisation. The applicant for this medicinal product is UCB Pharma S.A.

Lacosamide UCB will be available as a 10 mg/ml solution for infusion, a 10 mg/ml syrup, and 50 mg, 100 mg, 150 mg and 200 mg film-coated tablets. The active substance of Lacosamide UCB is lacosamide, anti-epileptic medicinal product (ATC code: N03AX18). A dual mode of action is hypothesised: it selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilization of hyperexcitable physiological neuronal excitability. In addition, it interacts with collapsin response mediator protein-2, a protein mainly expressed in the central nervous system and involved in neuronal differentiation and axonal outgrowth.

The benefits with Lacosamide UCB are its antiepileptic effects as adjunctive treatment of partial seizures. The most common side effects are dizziness, headache, diplopia and nausea.

The application for Lacosamide UCB was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Lacosamide UCB is Vimpat.

The full indication is:

> "Lacosamide UCB is indicated as monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union