27 January 2022
EMA/CHMP/37452/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Lacosamide UCB

lacosamide

On 27 January 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Lacosamide UCB. The marketing authorisation holder for this medicinal product is UCB Pharma S.A.

The CHMP adopted an extension to an existing indication as follows:[2]

> 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~~ **2 years** of age with epilepsy.

For information, the full indications for Lacosamide UCB will be as follows:

> Lacosamide UCB is indicated as monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from ~~4 years~~ **2 years** of age with epilepsy.
>
> Lacosamide UCB is indicated as adjunctive therapy
>
> - in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from ~~4 years~~ **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 updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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] New text in bold, removed text as strikethrough

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