23 June 2022
EMA/CHMP/473504/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rayvow

lasmiditan

On 23 June 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rayvow, intended for the treatment of migraine. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Rayvow will be available as 50 mg, 100 mg and 200 mg film-coated tablets. The active substance of Rayvow is lasmiditan, a 5-hydroxytriptamine 1F (5-HT_{1F}) receptor agonist (ATC code: N02CC), effecting a decrease of neuropeptide release and an inhibition of pain pathways.

The benefits of Rayvow is its ability to reduce migraine pain. The most common side effects are dizziness, somnolence and fatigue.

The full indication is:

> Rayvow is indicated for the acute treatment of the headache phase of migraine attacks, with or without aura in adults.

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

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