



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 February 2022  
EMA/CHMP/106030/2022  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Vydura rimegepant

On 24 February 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 Vydura, intended for the prophylaxis and acute treatment of migraine.

The applicant for this medicinal product is Biohaven Pharmaceutical Ireland DAC.

Vydura will be available as 75 mg oral lyophilisate. The active substance of Vydura is rimegepant, an analgesic (ATC code: N02CD06) which works as an antagonist of calcitonin gene-related peptide (CGRP).

The benefits of Vydura are pain relief in acute migraine and reduction in monthly migraine days in prevention trials. The most common side effect is nausea.

The full indication is:

Vydura is indicated for the

- Acute treatment of migraine with or without aura in adults;
- Preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month.

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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

