



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 February 2022  
EMA/CHMP/107869/2022  
Committee for Medicinal Products for Human Use (CHMP)

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

---

### Kapruvia difelikefalin

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 Kapruvia, intended for treatment of moderate-to-severe pruritus associated with chronic kidney disease.

The applicant for this medicinal product is Vifor Fresenius Medical Care Renal Pharma France.

Kapruvia will be available as 50 µg/ml solution for injection. The active substance of Kapruvia is difelikefalin, which is classified as other therapeutic product (ATC code: V03AX04) and is a selective agonist of the kappa opioid receptor, which can reduce itching and produce immunomodulatory effects when activated.

The benefits of Kapruvia are a reduction in itch intensity and improvement in itch-related quality of life over 12 weeks. The most common side effects are hyperkalaemia, somnolence, paraesthesia and dizziness.

The full indication is:

Kapruvia is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis.

Kapruvia should be restricted for in-centre haemodialysis use only. Kapruvia is intended for use by healthcare professionals experienced in the diagnosis and treatment of conditions for which difelikefalin is indicated.

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.

---

<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

