9 November 2023
EMA/CHMP/489254/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Evkeeza

evinacumab

On 9 November 2023, 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 Evkeeza. The marketing authorisation holder for this medicinal product is Ultragenyx Germany GmbH.

The CHMP adopted an extension to the existing indication to include treatment of patients aged 5 years and older with homozygous familial hypercholesterolaemia (HoFH). For information, the full indications for Evkeeza will be as follows:[2]

> Evkeeza is indicated as an adjunct to diet and other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and ~~adolescent~~paediatric patients aged 5~~12~~ years and older with homozygous familial hypercholesterolaemia (HoFH).

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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