



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 March 2026  
EMADOC-1700519818-3013044  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Lojuxta lomitapide

On 26 March 2026, 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 Lojuxta. The marketing authorisation holder for this medicinal product is Chiesi Farmaceutici S.p.A.

The CHMP adopted a change to the existing indication as follows:<sup>2</sup>

Lojuxta is indicated as an adjunct to a low-fat diet and other lipid-lowering medicinal products with or without low density lipoprotein (LDL) apheresis **for the treatment of in-adult and paediatric patients aged 5 years and older** ~~patients~~ with homozygous familial hypercholesterolaemia (HoFH).

Genetic confirmation of HoFH should be obtained whenever possible. Other forms of primary hyperlipoproteinemia and secondary causes of hypercholesterolaemia (e.g. nephrotic syndrome, hypothyroidism) must be excluded.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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

<sup>2</sup> New text in bold, removed text as strikethrough

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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