23 July 2026
EMADOC-1829012207-57694
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Evlarco

obicetrapib / ezetimibe

On 23 July 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Evlarco, intended for the treatment of primary hypercholesterolaemia or mixed dyslipidaemia.

The applicant for this medicinal product is A. Menarini International Licensing S.A.

Evlarco will be available as 10 mg / 10 mg film-coated tablets. The active substances of Evlarco are obicetrapib and ezetimibe, both lipid-modifying agents (ATC code: C10BA17). Obicetrapib blocks a blood protein called CETP thereby lowering the level of LDL cholesterol. Ezetimibe blocks a protein in the gut wall (NPC1L1) that absorbs cholesterol from food and bile, leading to decreased blood levels of LDL cholesterol.

The benefit of Evlarco is that it lowers LDL cholesterol ("bad" cholesterol) compared with placebo, as observed in 12-week randomised, double-blind, placebo-controlled study in adults with high cholesterol and/or atherosclerotic cardiovascular disease or multiple atherosclerotic cardiovascular disease risk factors who were already receiving the maximum tolerated cholesterol-lowering treatment. The most common side effects are hypertension, dizziness, headache, diarrhoea and abdominal pain.

The full indication is:

> Evlarco is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
>
> - in combination with a statin in patients unable to reach low-density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin in addition to ezetimibe or,
> - alone in patients who are either statin-intolerant or for whom a statin is contraindicated and are unable to reach LDL-C goals with ezetimibe alone or,
> - in patients already being treated with the combination of obicetrapib and ezetimibe as

[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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separate tablets with or without statin.

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