23 July 2026
EMADOC-1829012207-57693
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ubeslo

Obicetrapib

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 Ubeslo, intended for the treatment of primary hypercholesterolaemia or mixed dyslipidaemia.

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

Ubeslo will be available as 10 mg film-coated tablets. The active substance of Ubeslo is obicetrapib, a lipid-modifying agent (ATC code: C10AX22) that blocks a blood protein called CETP, thereby lowering the level of LDL cholesterol.

The benefit of Ubeslo is that it lowers LDL cholesterol ("bad" cholesterol) compared with placebo, as observed in two 52-week, randomised, double-blind, placebo-controlled studies in adults with high cholesterol and/or mixed dyslipidaemia who were already receiving the maximum tolerated cholesterol-lowering treatment. The most common side effects with Ubeslo are hypertension, dizziness, headache, diarrhoea and abdominal pain.

The full indication is:

> Ubeslo 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 or statin with other lipid-lowering therapies in patients unable to reach low-density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or,
> - alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

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

[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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languages after the marketing authorisation has been granted by the European Commission.