EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2026
EMADOC-1700519818-3316327
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Repatha

evolocumab

On 23 July 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 Repatha. The marketing authorisation holder for this medicinal product is Amgen Europe B.V..

The CHMP adopted an extension to the existing indication as follows:[2]

> ~~Established a~~**A**therosclerotic cardiovascular disease
>
> Repatha is indicated in adults with established **or at high risk for** atherosclerotic cardiovascular disease ~~(myocardial infarction, stroke or peripheral arterial disease)~~ to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:
>
> in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,
>
> alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.
>
> For study results with respect to effects on LDL-C, cardiovascular events and populations studied see section 5.1.

For information, the full indications for Repatha will be as follows:[2]

Hypercholesterolaemia and mixed dyslipidaemia

Repatha is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, and in paediatric patients aged 10 years and over with heterozygous familial hypercholesterolaemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach

[1] Summary 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 in strikethrough.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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.

Homozygous familial hypercholesterolaemia

Repatha is indicated in adults and paediatric patients aged 10 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies.

~~Established a~~**A**therosclerotic cardiovascular disease

Repatha is indicated in adults with established **or at high risk for** atherosclerotic cardiovascular disease ~~(myocardial infarction, stroke or peripheral arterial disease)~~ to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:

in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,

alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

For study results with respect to effects on LDL-C, cardiovascular events and populations studied see section 5.1.

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.

[1] Summary 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union