30 January 2020
EMA/CHMP/44961/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nilemdo

bempedoic acid

On 30 January 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nilemdo, intended for the treatment of adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia. The applicant for this medicinal product is FGK Representative Service GmbH.

Nilemdo will be available as 180 mg film-coated tablets. The active substance of Nilemdo is bempedoic acid, a lipid modifying agent (ATC code: C10AX15). Bempedoic acid lowers low-density lipoprotein cholesterol (LDL-C) by inhibiting cholesterol synthesis in the liver.

The benefits with Nilemdo are its ability to reduce levels of LDL-C but also non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apo B), and total cholesterol (TC) in patients with hypercholesterolaemia or mixed dyslipidaemia when administered alone and in combination with other lipid-modifying medicinal products. The most common side effects are hyperuricaemia, pain in extremity, and anaemia.

The full indication is:

> "Nilemdo is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
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> - in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin (see sections 4.2, 4.3, and 4.4) 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 in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been

[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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