30 January 2020 *corr[i]
EMA/CHMP/44979/2020
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Nustendi

## bempedoic acid / ezetimibe

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 Nustendi, intended for the treatment of primary hypercholesterolaemia and mixed dyslipidaemia. The applicant for this medicinal product is FGK Representative Service GmbH.

Nustendi will be available as 180 mg / 10 mg film-coated tablets. The active substances of Nustendi are the lipid modifying agents bempedoic acid and ezetimibe. These two low-density lipoprotein (LDL-C) lowering compounds have complementary mechanisms of action. Bempedoic acid reduces LDL-C by inhibiting cholesterol synthesis in the liver, while ezetimibe reduces cholesterol absorption in the intestine.

The benefits with Nustendi 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 and constipation.

The full indication is:

> "Nustendi 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 LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe (see sections 4.2, 4.3, and 4.4),
> - 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,
> - in patients already being treated with the combination of bempedoic acid and ezetimibe as 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 in the European public assessment report (EPAR) and

[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

**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

made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[i] *corr 2 April 2020 to remove incorrect atc code