21 March 2024
EMA/CHMP/115796/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Nustendi

bempedoic acid / ezetimibe

On 21 March 2024, 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 Nustendi. The marketing authorisation holder for this medicinal product is Daiichi Sankyo Europe GmbH.

The CHMP adopted a new indication as follows:

Cardiovascular disease

Nustendi is indicated in adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:

- in patients on a maximum tolerated dose of a statin and not adequately controlled with additional ezetimibe treatment or,
- in patients who are either statin-intolerant, or for whom a statin is contraindicated, and not adequately controlled with ezetimibe treatment or,
- in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets.

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 Nustendi will be as follows[2]:

Hypercholesterolaemia and mixed dyslipidaemia

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

[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
[2] New text in bold

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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.

Cardiovascular disease

Nustendi is indicated in adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:

- **in patients on a maximum tolerated dose of a statin and not adequately controlled with additional ezetimibe treatment or,**
- **in patients who are either statin-intolerant, or for whom a statin is contraindicated, and not adequately controlled with ezetimibe treatment or,**
- **in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets.**

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 in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.