

Public Summary SwissPAR dated 6 April 2021

## Nilemdo<sup>®</sup> (active substance: bempedoic acid)

First authorisation in Switzerland: 14 December 2020

Medicine (film-coated tablets) for lowering blood lipid levels

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### About the medicinal product

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The medicinal product Nilemdo, containing the active substance bempedoic acid, is used to lower an elevated level of cholesterol in the blood (= hypercholesterolaemia) in adults whose elevated cholesterol levels cannot be lowered sufficiently with drugs such as statins.

Nilemdo is used as an adjunct to diet and in combination with a statin or other medicine for lowering a high cholesterol level.

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### Mode of action

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The active substance bempedoic acid decreases the production of cholesterol in the liver by blocking an enzyme called ATP cit-

rate lyase. Bempedoic acid thereby also promotes the lowering of the LDL-cholesterol level in the blood.

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### Use

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Nilemdo film-coated tablets containing 180 mg of bempedoic acid are available on prescription only. The usual dosage of Nilemdo

is 180 mg once daily. It is taken between meals. The tablet should not be chewed.

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### Efficacy

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The efficacy of Nilemdo was investigated in two 52-week studies with 3,009 adult patients. The participants were suffering either from elevated cholesterol levels in the blood or the build-up of excessive fatty deposits in the blood vessels (atherosclerotic cardiovascular disease). Before starting the study, the

participants had already been treated with a maximum tolerated statin dose and, in some cases, other cholesterol-lowering medicines. In the studies, a third of the participants received a placebo (dummy drug), while the other two thirds received 180 mg of Nilemdo per day. After 12 weeks, reductions in the

LDL-cholesterol level of 17% in the first study and 18% in the second study were observed with Nilemdo compared to placebo.

The observed effect was maintained until the end of the study after 52 weeks.

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## Precautions, undesirable effects & risks

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Nilemdo may not be used in those who are hypersensitive to bempedoic acid or any of the excipients.

Side effects of Nilemdo can include a raised uric acid level in the blood or pains in the arms or legs.

Pregnant or breastfeeding women should not take Nilemdo. Women of childbearing

age must use an effective method of contraception.

All precautions, risks and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

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## Why the medicine has been authorised

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The studies showed that, in adult patients with an elevated blood cholesterol level or a build-up of excessive fatty deposits in the blood vessels (atherosclerotic cardiovascular disease) who still required additional lowering of the LDL-cholesterol level despite previous treatment, the daily administration of 180 mg Nilemdo managed to lower the cholesterol level in the blood.

Taking all the risks and precautions into account, and based on the available data, the benefits of Nilemdo outweigh the risks. Swissmedic has therefore authorised the medicine Nilemdo with the active substance bempedoic acid for use in Switzerland.

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## Further information on the medicinal product

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Information for healthcare professionals: [Information for healthcare professionals Nilemdo®](#)

Information for patients (package leaflet): [Information for patients Nilemdo®](#)

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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