swissmedic

Summary report on authorisation dated 6 June 2025

Nilemdo® (active substance: bempedoic acid)

Indication extension in Switzerland: 31 January 2025

Film-coated tablets for the treatment of adults with primary hypercholesterolaemia or mixed dyslipidaemia, as an adjunct to diet, either alone or in combination with a statin or other lipid-lowering therapies, as well as to reduce cardiovascular risk in adults with established, or at high risk for, atherosclerotic cardiovascular disease.

About the medicinal product

Nilemdo, containing the active ingredient bempedoic acid, is used to treat adults with primary hypercholesterolaemia (high blood cholesterol levels) of familial and non-familial origin and adults with mixed dyslipidaemia (uncontrolled fat metabolism disorder).

Nilemdo is used as an adjunct to diet – either alone or in combination with statins or other lipid-lowering therapies. It is used particularly in patients who are not achieving their cholesterol targets, despite taking the maximum tolerable dose of statins, or who cannot take statins.

Nilemdo is also used to reduce the risk of cardiovascular events in adults in whom there is an established or elevated likelihood of atherosclerotic cardiovascular disease by lowering LDL cholesterol. In this case, it can be used alone or in combination with ezetimibe or in combination with a statin – with or without ezetimibe.

Swissmedic first approved Nilemdo on 14 December 2020 for the treatment of adults with high blood cholesterol levels that cannot be adequately reduced using medicines such as statins and who are at high risk of developing cardiovascular disease.

With the extensions of its indication dated 31 January 2025, Nilemdo can now also be used in dyslipidaemia and without the addition of statins. Furthermore, Nilemdo can now also be used to lower the risk of cardiovascular events.

In deciding whether to authorise the indication extensions for Nilemdo, Swissmedic took into account the assessment of the European Medicines Agency (EMEA/H/C/004958/II/0031) and the corresponding medicinal product information texts.

Since the assessment of the clinical data was based on the assessment reports of this foreign authority, the preconditions for a full SwissPAR (Swiss Public Assessment Report – a detailed report for professionals) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisations of the foreign reference authorities.

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Nilemdo®

Information for patients (package leaflet): Patient information Nilemdo®
Healthcare professionals 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 Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.