Summary of risk management plan for NILEMDO (Bempedoic acid)

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Disclaimer

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them. The RMP summary of NILEMDO is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization. Please note that the reference document which is valid and relevant for the effective and safe use of NILEMDO in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Daiichi Sankyo (Schweiz) AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of NILEMDO.

Summary of risk management plan for Nilemdo (Bempedoic acid)

This is a summary of the risk management plan (RMP) for Nilemdo. There are no important identified risks or important potential risks for bempedoic acid. The RMP details how more information will be obtained about Nilemdo's risks and uncertainties (missing information).

Nilemdo's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Nilemdo should be used.

This summary of the RMP for Nilemdo should be read in the context of all this information, including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Nilemdo's RMP.

I. The Medicine and What It Is Used For

Nilemdo is authorized for treatment of primary hypercholesterolemia in adults, as an adjunct to diet and is authorized as a treatment to reduce cardiovascular risk in adults with established or at high risk for atherosclerotic cardiovascular disease by lowering LDL-C levels, as an adjunct to correction of other risk factors (see SmPC for the full indication). It contains bempedoic acid as the active substance and it is given by mouth.

Further information about the evaluation of Nilemdo's benefits can be found in Nilemdo's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https :// www .ema .europa .eu / en / medicines / human / EPAR / nilemdo.

II. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

There are no important identified risks or important potential risks for Nilemdo. Routine risk minimization measures and pharmacovigilance activities are planned for all safety concerns.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals
- Important advice on the medicine's packaging
- The authorized pack size—the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly
- The medicine's legal status—the way a medicine is supplied to the patient (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including PBRER assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Nilemdo is not yet available, it is listed under "missing information" below.

II.A List of Important Risks and Missing Information

Important risks of Nilemdo are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with

the use of Nilemdo. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (eg, on the long-term use of the medicine).

List of Important Identified and Potential Risks and Missing Information	
Important identified risk	Not applicable
Important potential risks	Not applicable
Missing information	Use in patients with patients with severe renal impairment and patients with end-stage renal disease receiving dialysis

II.B Summary of Important Risks

Missing Information: Use in Patients With Severe Renal Impairment and in Patients With End-Stage Renal Disease Receiving Dialysis	
Risk minimization measures	Routine risk minimization measures SmPC Sections 4.4 and 5.2 PIL Section 2 Additional risk minimization measures None
Additional pharmacovigilance activities	Phase 1, open-label, single-dose, parallel-group study to evaluate the effects of ESRD and ESRD requiring dialysis on the PK of bempedoic acid. See Section II.C of this summary for an overview of the postauthorization development plan.

II.C. Post-authorization Development Plan

II.C.1 Studies That Are Conditions of the Marketing Authorization

There are no studies that are conditions of the marketing authorization or specific obligation for Nilemdo.

II.C.2 Other Studies in Post-authorization Development Plan

Short Title	Effects of ESRD and ESRD requiring dialysis on the PK of bempedoic acid (study 1002-071)
Purpose of the Study	Primary objectives: • To characterize the PK of ETC-1002, ESP15228, and ETC-1002-glucuronide in subjects with normal renal function, ESRD, and ESRD requiring dialysis following single-dose bempedoic acid administration Secondary objectives: • To evaluate the safety and tolerability of a single dose of bempedoic acid 180 mg in subjects with normal renal function, ESRD, and ESRD requiring dialysis. Safety concern addressed: use in patients with severe renal impairment and in patients with ESRD receiving dialysis (note: only part of the safety concern, patients with severe ESRD and ESRD requiring dialysis, is addressed by this study)