Based on EU RMP Version 4.0
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Public Risk Management Plan (RMP) Summary

CHOLIB® (fenofibrate/simvastatin) Tablets

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 **CHOLIB®** 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 CHOLIB® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Mylan Pharma GmbH is fully responsible for the accuracy and correctness of the content of the published summary RMP of CHOLIB®.

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SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Cholib® (Fenofibrate/Simvastatin)

This is a summary of the risk management plan (RMP) for Cholib®. The RMP details important risks of fenofibrate/simvastatin, how these risks can be minimised, and how more information will be obtained about fenofibrate/simvastatin's risks and uncertainties (missing information).

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

This summary of the RMP for Cholib® should be read in the context of all the 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 Cholib®'s RMP.

I. The Medicine and What it is Used For

Cholib® is indicated 'as adjunctive therapy to diet and exercise in high cardiovascular risk adult patients with mixed dyslipidemia to reduce triglycerides and increase HDL-C levels when LDL-C levels are adequately controlled with the corresponding dose of simvastatin monotherapy 20 mg or 40 mg' in the EEA. It contains fenofibrate/simvastatin as the active substance, and it is given by oral route.

Further information about the evaluation of Cholib®'s benefits can be found in Cholib®'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Cholib®, together with measures to minimise such risks and the proposed studies for learning more about Cholib®'s risks, are outlined below.

Measures to minimise 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 authorised 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

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

II.A List of Important Risks and Missing Information

Important risks of Cholib® are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Cholib®. 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 (e.g., on the long-term use of the medicine/use in special patient populations etc.);

Summary of safety concerns

List of Important Risks and Missing Information	
Important Identified Risks	None
Important Potential Risks	None
Missing Information	None

II.B Summary of Important Risks

The important risks are well described in the proposed product information and appropriately managed by routine pharmacovigilance activities and risk minimisation measures already in place.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Cholib®.

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

There are no studies required for Cholib®.