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Swiss Summary of the Risk Management Plan (RMP) for Repatha® (Evolocumab)

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 minimize them.

The RMP summary of REPATHA® 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 REPATHA® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

AMGEN Switzerland AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of REPATHA®.

Overview of disease epidemiology

Repatha is indicated as adjunct to diet and maximally tolerated statin with or without additional lipid lowering therapy, for the treatment of:

- adults with hypercholesterolaemia (including heterozygous familial hypercholesterolaemia),
- paediatric patients aged 10 years with heterozygous familial hypercholesterolaemia
- adults and paediatric patients aged 10 years with homozygous familial hypercholesterolaemia

who require additional lowering of LDL cholesterol (LDL-C).

Repatha is indicated to reduce the risk of cardiovascular events (myocardial infarction, stroke, and coronary revascularisation) in patients with high cardiovascular risk. For effects on cardiovascular mortality, see "Properties/Effects.

It contains evolocumab as the active substance and it is given by subcutaneous injection.

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

Risks associated with the medicine and activities to minimize or further characterize the risks

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

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 public (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 events is collected continuously and regularly analyzed, including PSUR 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 Repatha is not yet available, it is listed under "missing information" below.

List of Important Risks and Missing Information

Important risks of Repatha are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. 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 Repatha.

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 risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	• Use in pregnant/lactating women • Long-term use including effects of low-density lipoprotein cholesterol < 40 mg/dL (< 1.03 mmol/L)

Summary of Important Risks

Missing information: Use in pregnant/lactating women	
Risk minimization measures	Routine risk minimization measures • To be found in relevant sections of product information, where advice is given that Repatha should not be used during pregnancy unless the clinical condition of the woman requires treatment with evolocumab • Relevant section of patient information Additional risk minimization measures: • None.

Missing Information: Long-term use including effects of low-density lipoprotein cholesterol < 40 mg/dL or < 1.03 mmol/L	
Risk minimization measures	Routine risk minimization measures: • To be found in relevant section of product information Additional risk minimization measures: • None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: • Study 20130295 • Study 20160250 See *Postauthorization Development Plan* of this summary for an overview

Postauthorization Development Plan

Studies Which Are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Repatha.

Other Studies in Postauthorization Development Plan

Study Short Name	Purpose of the Study
Study 20130295:	To characterize the safety and tolerability of extended long-term administration of evolocumab in subjects having received evolocumab or placebo in the completed FOURIER trial Safety concerns addressed: Long-term use including effects of LDL-C < 40 mg/dL or < 1.03 mmol/L
Study 20160250:	To describe the safety and tolerability of long-term administration of evolocumab in a cohort of Western European subjects having received evolocumab or placebo in the completed FOURIER trial Safety concerns addressed: Long-term use including effects of LDL-C < 40 mg/dL or < 1.03 mmol/L

Summary of changes to the risk management plan over time

Major changes to the Risk Management Plan over time

Version	Approval Date Procedure	Change
7.1	29 July 2021 To be confirmed by EMA	• Proposed indication updated. Paediatric patients with heterozygous familial hypercholesterolaemia grouped under the indication 'Hypercholesterolaemia and mixed dyslipidaemia'.

This summary was last updated in June 2022.