Summary of the Risk Management Plan
for
LIVMARLI® (Maralixibat Chloride)

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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 LIVMARLI 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 authorisation.

Please note that the reference document which is valid and relevant for the effective and safe use of LIVMARLI in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorised by Swissmedic.

Mirum Pharmaceuticals AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of LIVMARLI.

Summary of risk management plan for Livmarli (maralixibat chloride)

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

Livmarli's product information gives essential information to healthcare professionals and patients on how Livmarli should be used.

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

I. The medicine and what it is used for

Livmarli is authorised in patients 3 months of age and older for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) (see the SmPC for the full indication). It contains maralixibat chloride as the active substance and it is given by the oral route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Livmarli, together with measures to minimise such risks and the proposed studies for learning more about Livmarli'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 product information 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 to ensure that the medicine is used correctly;
- The medicine's legal status—the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report assessment, so that timely and appropriate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Livmarli are risks that need special risk management activities to further investigate or minimise 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 Livmarli. 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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

None.

II.C.2 Other studies in post-authorisation development plan

None.