Summary of the Risk Management Plan for

XIFAXAN 550 mg film-coated tablets

Active substance: rifaximin

Document version: 1.0

Marketing Autorisation Holder: Alfasigma Schweiz AG (Alfasigma's Affiliate)

Document Date: 05/06/2023

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 XIFAXAN 550 mg film-coated tablets 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 XIFAXAN 550 mg film-coated tablets in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Alfasigma Schweiz AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of XIFAXAN 550 mg film-coated tablets.

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Part VI: Summary of the risk management plan

Summary of risk management plan for rifaximin 200 mg / 400 mg / 550 mg film-coated tablets and 2 g/100 mL granules for oral suspension

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

Rifaximin's SmPC and its package leaflet give essential information to healthcare professionals and patients on how rifaximin should be used.

I. The medicine and what it is used for

Rifaximin 200 mg / 400 mg film-coated tablets and 2 g/100 mL granules for oral suspension are indicated for the treatment of different gastrointestinal conditions, such as intestinal infections (see SmPC and PIL for the full indication). Instead, rifaximin 550 mg film-coated tablets is intended for the reduction in recurrence of episodes of overt Hepatic Encephalopathy (HE) in patients ≥ 18 years of age.

It contains rifaximin as the active substance and it is given by oral route of administration.

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

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

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

- Specific information, including warnings, precautions, and advice on correct use, are reported in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice is also reported on the medicine's packaging;
- Rifaximin can only be administered with prescription of a healthcare professional.

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

II.A List of important risks and missing information

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

No important risks have been identified for rifaximin.

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 rifaximin.

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

There are no studies required for rifaximin.