LOKELMA™

powder for oral suspension
10 g and 5 g

Summary of the Risk Management Plan (RMP) for LOKELMA™ (natrii zirconia cyclosilicas)

Document Version: 1.0

Document Date: 16 April 2021

Based on EU RMP Version Number 2, Succession Number 2, 07 October 2019 (Data lock point 21 March 2019)

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 LOKELMA™ 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 LOKELMA™ in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. AstraZeneca AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of LOKELMA™.

1. THE MEDICINE AND WHAT IT IS USED FOR

LOKELMA is authorised for the treatment of hyperkalaemia in adult patients. It contains sodium zirconium cyclosilicate as a powder, which is suspended in water and swallowed.

2. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of LOKELMA together with measures to minimise such risks and the proposed studies for learning more about LOKELMA'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 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 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 so that immediate action may be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

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

2.1 List of important risks and missing information

Important risks of LOKELMA are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product may be safely administered. Important risks may be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of LOKELMA. 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).

Table 1 List of Important Risks and Missing Information

Important Identified Risks	None
Important Potential Risks	None
Missing Information	None

2.2 Summary of important risks

None

Important Potential Risks

None

3. POST-AUTHORISATION DEVELOPMENT PLAN

3.1 Studies which are conditions of the marketing authorisation

There are no studies that are conditions of the marketing authorisation or specific obligations for LOKELMA.

3.2 Other studies in post-authorisation development plan

There are no studies required for LOKELMA.