Name of product: Sedaconda (isoflurane)

RMP version to be assessed as part of this application: 1.0

Name of the Marketing Authorisation Holder: Sedana Medical

Date: 23.09.2022

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 "name of the medicinal product" 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 "name of the medicinal product" in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. "Name of the marketing authorisation holder" is fully responsible for the accuracy and correctness of the content of the published summary RMP of "name of the medicinal product". The RMP Summary will be checked formally by Swissmedic and, provided there is no cause for complaint, published on the Swissmedic website with a link in www.swissmedicinfo.ch. The marketing authorisation holder will not be informed individually. In the event of a complaint, the marketing authorisation holder will be contacted.

Part VI: Summary of the risk management plan

Summary of risk management plan for Sedaconda (isoflurane)

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

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

I. The medicine and what it is used for

Sedaconda is authorised for sedation of mechanically ventilated adult patients during intensive care. It contains isoflurane as the active substance and it is given by inhalation.

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

Important risks of Sedaconda, together with measures to minimise such risks and the proposed studies for learning more about Sedaconda '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 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 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 Sedaconda is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Sedaconda 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 Sedaconda. 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	Long-term use > 48 hours

II.B Summary of important risks

Missing information: Long-term use > 48 hours	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 Additional risk minimisation measures: None

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 Sedaconda.

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

There are no studies required for Sedaconda.