Part VI: Summary of the risk management plan

RMP Part VI is valid for all products in this RMP:

Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion

Dexmedetomidine EVER Pharma 100 micrograms/ml

Summary of risk management plan for Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion / Dexmedetomidine EVER Pharma 100 micrograms/ml (dexmedetomidine)

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

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

I. The medicine and what it is used for

Dexmedetomidine EVER Pharma is authorised for sedation (see SmPC for the full indication). It contains dexmedetomidine as the active substance and it is given by diluted intravenous infusion.

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

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

II.A List of important risks and missing information

Important risks of Dexmedetomidine EVER Pharma 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 Dexmedetomidine EVER Pharma. 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	• Atrioventricular block • Bradycardia • Cardiac arrest • Hypotension • Hypertension • Hyperglycaemia • Withdrawal syndrome
Important potential risks	• Rhabdomyolysis • Torsade de pointes/QT prolongation • Overdose • Off-label use • Increased mortality in younger ICU patients
Missing information	• Pregnancy

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 Dexmedetomidine.

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

There are no studies required for Dexmedetomidine.