Part VI: Summary of the risk management plan for Dexmedetomidine Kabi

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

Dexmedetomidine SmPC and its PL give essential information to healthcare professionals and patients on how Dexmedetomidine should be used.

Important new safety concerns will be included in updates of the Dexmedetomidine RMP.

I. The medicine and what it is used for

Dexmedetomidine is indicated for:

- Sedation of adult ICU (Intensive Care Unit) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale (RASS) 0 to -3).
- Sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e. procedural/awake sedation.

It contains dexmedetomidine (as hydrochloride) as an active substance and it should only be administered as a diluted intravenous infusion using a controlled infusion device.

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

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 Kabi is not yet available, it is listed under "missing information" outlined in the next section.

II.A List of important risks and missing information

Important risks of Dexmedetomidine 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. 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	Bradycardia Hypotension Hypertension Hyperglycaemia Withdrawal syndrome
Important potential risks	Atrioventricular block Ischaemic heart disease Cortisol suppression Convulsions Hypothermia Respiratory depression Cardiac arrest Torsade de pointes / QT prolongation Overdose Off-label use
Missing information	Pregnancy

II.B Summary of important risks

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

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 Kabi.

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

There are no on-going or closed studies for Dexmedetomidine Kabi.