PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Dexmedetomidine Hydrochloride (dexmedetomidine hydrochloride)

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

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

Important new concerns or changes to the current ones will be included in updates of Dexmedetomidine Hydrochloride's RMP.

I. The medicine and what it is used for

Dexmedetomidine Hydrochloride is authorized 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) and for sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e., procedural/awake sedation (see SmPC for the full indication). It contains dexmedetomidine hydrochloride as the active substance and it is given by intravenous infusion.

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

Important risks of Dexmedetomidine Hydrochloride, together with measures to minimise such 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, 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 Hydrochloride is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dexmedetomidine Hydrochloride 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 Hydrochloride. 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.

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 Hydrochloride.

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

There are no studies required for Dexmedetomidine Hydrochloride.