# PART VI Summary of the risk management plan

## Summary of risk management plan for Dexmedetomidine Kalceks (dexmedetomidine hydrochloride)

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

Summary of product characteristics (SPC) of **Dexmedetomidine Kalceks** and its package leaflet give essential information to healthcare professionals and patients on how **Dexmedetomidine Kalceks** should be used.

### I. The medicine and what it is used for

**Dexmedetomidine Kalceks** is authorised for sedation of adult ICU (Intensive Care Unit) patients (see SPC for the full indication). It contains dexmedetomidine hydrochloride as the active substance and it is administered as a diluted intravenous infusion using a controlled infusion device; each 1 ml of concentrate contains dexmedetomidine hydrochloride equivalent to 100 micrograms dexmedetomidine and each 2 ml ampoule contains 200 micrograms of dexmedetomidine.

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

Important risks of **Dexmedetomidine Kalceks**, together with measures to minimise such risks and the proposed studies for learning more about risks of **Dexmedetomidine Kalceks**, 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 SPC 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.

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

## II.A *List of important risks and missing information*

Important risks of **Dexmedetomidine Kalceks** 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 Kalceks**. 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 Summary of the RMP - List of important risks and missing information

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|---|---|
| **Important identified risks** | Bradycardia<br>Hypotension<br>Hypertension<br>Hyperglycaemia<br>Withdrawal syndrome |
| **Important potential risks** | Atrioventricular block<br>Ischaemic heart disease<br>Cortisol suppression<br>Convulsions<br>Hypothermia<br>Respiratory depression<br>Cardiac arrest<br>Torsade de pointes/QT prolongation<br>Overdose<br>Off-label use |
| **Missing information** | Use in 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*

Not applicable.