Summary of risk management plan for Dexmedetomidine B. Braun 100 µg/ml concentrate for solution for infusion (dexmedetomidine)

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

Dexmedetomidine B. Braun's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dexmedetomidine B. Braun should be used. This summary of the RMP for Dexmedetomidine B. Braun should be read in the context of all this information.

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

I. The medicine and what it is used for

Dexmedetomidine B. Braun is authorised for sedation of adult Intensive Care Unit (ICU) 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 as the active substance and it is given by intravenous infusion using a controlled infusion device.

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

Important risks of Dexmedetomidine B. Braun, together with measures to minimise such risks and the proposed studies for learning more about Dexmedetomidine B. Braun’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.

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

II.A List of important risks and missing information

Important risks of Dexmedetomidine B. Braun 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 B. Braun. 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

List of important risks and missing information	
Missing information	• Use in pregnancy

II.B Summary of important risks

Important identified risk: Bradycardia	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.2, 4.4, 4.5 and 4.8 • PL sections 2, 3 and 4 Additional risk minimisation measures: *No risk minimisation measures*
Important identified risk: Hypotension	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.2, 4.3, 4.4, 4.5 and 4.8 • PL sections 2, 3 and 4 Additional risk minimisation measures: *No risk minimisation measures*
Important identified risk: Hypertension	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.2, 4.4 and 4.8 • PL sections 3 and 4 Additional risk minimisation measures: *No risk minimisation measures*
Important identified risk: Hyperglycaemia	
Risk minimisation measures	Routine risk minimisation measures: • SmPC section 4.8

	• PL section 4 Additional risk minimisation measures: *No risk minimisation measures*
Important potential risk: Withdrawal syndrome	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.4 and 4.8 • PL section 4 Additional risk minimisation measures: *No risk minimisation measures*
Important potential risk: Atrioventricular block	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.3, 4.4 and 4.8 • PL sections 2 and 4 Additional risk minimisation measures: *No risk minimisation measures*
Important potential risk: Ischaemic heart disease	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.4 and 4.8 • PL sections 2 and 4 Additional risk minimisation measures: *No risk minimisation measures*
Important potential risk: Cortisol suppression	
Risk minimisation measures	Routine risk minimisation measures: • SmPC section 5.1 Additional risk minimisation measures:

	No risk minimisation measures
Important potential risk: Convulsions	
Risk minimisation measures	Routine risk minimisation measures: • SmPC section 4.4 Additional risk minimisation measures: *No risk minimisation measures*
Important potential risk: Hypothermia	
Risk minimisation measures	Routine risk minimisation measures: • SmPC section 5.1 Additional risk minimisation measures: *No risk minimisation measures*
Important potential risk: Respiratory depression	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.2, 4.4, 4.5, 4.8 and 5.1 • PL section 4 Additional risk minimisation measures: *No risk minimisation measures*
Important potential risk: Cardiac arrest	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.4, 4.8 and 4.9 • PL sections 2 and 4 Additional risk minimisation measures: *No risk minimisation measures*
Important potential risk: Torsade de pointes/QT prolongation	
Risk minimisation measures	Routine risk minimisation measures:

	No risk minimisation measures Additional risk minimisation measures: *No risk minimisation measures*
Important potential risk: Overdose	
Risk minimisation measures	Routine risk minimisation measures: ● SmPC sections 4.2, 4.9 and 6.6 Additional risk minimisation measures: *No risk minimisation measures*
Important potential risk: Off-label use	
Risk minimisation measures	Routine risk minimisation measures: ● SmPC sections 4.1, 4.2 and 4.4 ● PL sections 1 and 3 Additional risk minimisation measures: *No risk minimisation measures*
Additional pharmacovigilance activities	There is an ongoing/planned clinical study for an originator medicinal product to assess and characterise this risk, in order to evaluate the safety and efficacy of dexmedetomidine. B. Braun will not perform any non-clinical, clinical or epidemiological study, but will duly consider all conclusions from that performed for an originator medicinal product. Routine pharmacovigilance activities will be ensured.
Important potential risk: Use in pregnancy	
Risk minimisation measures	Routine risk minimisation measures: ● SmPC section 4.6 ● PL section 2 Additional risk minimisation measures:

	No risk minimisation measures

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 B. Braun.

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

There are no studies required for Dexmedetomidine B. Braun.