

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion**

This is a summary of the risk management plan (RMP) for Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion. The RMP details important risks of Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion, how these risks can be minimised, and how more information will be obtained about Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion's risks and uncertainties (missing information).

Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion should be used.

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

Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion is authorised 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). 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 infusion.

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

Important risks of Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion together with measures to minimise such risks and the proposed studies for learning more about Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion'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 so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

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

Important risks of Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion 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 EQL Pharma, 100 micrograms/ml concentrate for solution for infusion. 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);

<b>List of important risks and missing information</b>	
Important identified risks	<ul style="list-style-type: none"> <li>• Atrioventricular block</li> <li>• Cardiac arrest</li> <li>• Bradycardia</li> <li>• Hypotension</li> <li>• Hypertension</li> <li>• Hyperglycaemia</li> <li>• Withdrawal syndrome</li> </ul>
Important potential risks	<ul style="list-style-type: none"> <li>• Cortisol suppression</li> <li>• Convulsions</li> <li>• Hypothermia</li> <li>• Torsade de pointes/QT prolongation</li> <li>• Overdose</li> <li>• Off-label use</li> <li>• Increased mortality in younger ICU patients</li> <li>• Rhabdomyolysis</li> </ul>
Missing information	<ul style="list-style-type: none"> <li>• Pregnancy</li> </ul>

## **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 EQL Pharma, 100 micrograms/ml concentrate for solution for infusion.

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

There are no studies required for Dexmedetomidine EQL Pharma, 100 micrograms/ml concentrate for solution for infusion.