Part VI: Summary of the risk management plan

Summary of risk management plan for *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or infusion*

This is a summary of the risk management plan (RMP) for *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or infusion*. The RMP details important risks of *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or infusion* how these risks can be minimised, and how more information will be obtained about the products' risks and uncertainties (missing information).

The summary of product characteristics (SmPC) for *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or infusion* and the associated package leaflets give essential information to healthcare professionals and patients on how these products should be used.

I. The medicine and what it is used for

Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or infusion is authorised for use to prevent pain during the induction and maintenance of anaesthesia. It is also authorised to prevent pain in artificially ventilated adult intensive care patients.

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

Important risks of *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or infusion*, together with measures to minimise such risks and the proposed studies for learning more about the risks associated with treatment with *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or infusion*, 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 a 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 *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or infusion* is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or 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 *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or 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).

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

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 a specific obligation for *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or infusion.*

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

There are no studies required for *Remifentanil-hameln 1 mg, 2 mg, and 5 mg powder for concentrate for solution for injection or infusion*.