Part VI: Summary of the risk management plan

Summary of risk management plan for *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/infusion*

This is a summary of the risk management plan (RMP) for *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/infusion*. The RMP details important risks of *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/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 *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/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

Via the intravenous route of administration (i.e. by the administration of the medicinal product directly into a vein), *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/infusion* are authorised for use in adults in combination with other anaesthetics to prevent pain during the induction and maintenance of anesthesia, and for use on their own to induce and maintain anesthesia during major surgery. In children older than one month, *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/infusion* are authorised for use via the intravenous route to prevent pain during the induction and/or maintenance of balanced anaesthesia.

Via the epidural route of administration (i.e. by the administration of the medicinal product into the epidural space around the spinal cord), *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/infusion* are authorised for use in adults in combination with the medicinal product bupivacaine to prevent pain after surgery or Cesarean section, and during labour and childbirth.

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

Important risks of *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/infusion*, together with measures to minimise such risks and the proposed studies for learning more about the risks associated with treatment with *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/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 *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/infusion* is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/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 *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/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).

List of important risks and missing information	
Important identified risks	• Respiratory depression • Clonic movements • Muscle rigidity • Bradycardia and cardiac arrest • Hypotension • Drug dependence and withdrawal
Important potential risks	• Serotonin syndrome induced by interaction between sufentanil and serotonergic drugs (e.g. SSRI, MAO inhibitors) • Medication error
Missing information	• Intravenous use in children • Use during pregnancy and lactation

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 *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/infusion*.

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

There are no studies required for *Sufentanil-hameln 5 and 50 micrograms/ml solutions for injection/infusion*.