Part VI: Summary of the risk management plan

Summary of risk management plan for Sofentil (sufentanil)

This is a summary of the risk management plan (RMP) for Sofentil. The RMP contains details on important risks of Sofentil, how these risks can be minimised, and how more information will be obtained about Sofentil's risks and uncertainties (missing information).
Sofentil's summary of product characteristics (SmPC) and its package leaflet (PIL) give essential information to healthcare professionals and patients on how Sofentil should be used.

I. The medicine and what it is used for

Sofentil is indicated in adults in combined anesthesia and analgesia, epidural analgesia in the treatment of postoperative pain and supplementary analgesic agent to epidural administered bupivacaine. In pediatric population Sofentil in indicated intravenously as an analgesic during induction and/or maintenance of balanced general anesthesia in children over the age of 1 month and epidural for the postoperative management of pain following general surgical, thoracic or orthopaedic procedures in children aged 1 year and over (see the SmPC for the full indication).
Sofentil contains sufentanil as the active substance and is given by injection or infusion.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Sofentil, together with measures to minimize such risks are outlined below.
Measures to minimize 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 – this medicine is supplied to the patient only with a prescription this can help to minimise its risks.

Together, these measures constitute routine risk minimization 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.

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

II.A List of important risks and missing information

Important risks of Sofentil 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 Sofentil. 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.

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 symptoms
Important potential risks	• Medication error • Serotonin syndrome induced by interaction between sufentanil and serotonergic drugs (e.g. SSRI, MAO inhibitors)
Missing information	• Use during pregnancy and breastfeeding

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 Sofentil.

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

There are no studies required for Sofentil.