Part VI: Summary of the risk management plan

Summary of risk management plan for

Sufentanil Kalceks 5 micrograms/ml solution for injection/infusion
Sufentanil Kalceks 50 micrograms/ml solution for injection/infusion

(sufentanil citrate)

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

Sufentanil Kalceks's summary of product characteristics (SPC) of Sufentanil Kalceks and its package leaflet give essential information to healthcare professionals and patients on how Sufentanil Kalceks should be used.

Important new concerns or changes to the current ones will be included in updates of Sufentanil Kalceks's RMP.

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 Kalceks is authorised for use in anaesthesia during all surgical procedures in patients with endotracheal intubation receiving mechanical ventilation as an analgesic component during induction and maintenance of balanced anaesthesia and as an anaesthetic agent for induction and maintenance of anaesthesia in adults. In children over the age of one month, Sufentanil Kalceks is authorised for use via the intravenous route as an analgesic agent for use during induction and/or maintenance of balanced general 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 Kalceks is authorised for use as a supplementary analgesic agent to epidural bupivacaine for postoperative treatment of pain following general, thoracic and orthopaedic surgery and caesarean section and for treatment of pain during labour and vaginal delivery in adults. In children aged 1 year and older, Sufentanil Kalceks is authorised for use via the epidural route for the postoperative management of pain following general surgery, thoracic or orthopaedic procedures.

It contains sufentanil citrate as the active substance and it is given by intravenous or epidural route of administration in concentration of 5 or 50 micrograms per one millilitre.

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

Important risks of Sufentanil Kalceks, together with measures to minimise such risks and the proposed studies for learning more about risks of Sufentanil Kalceks, 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 SPC 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 Sufentanil Kalceks 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 Kalceks. 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 medical 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 Sufentanil Kalceks.

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

There are no studies required for Sufentanil Kalceks.