PART VI Summary of the risk management plan

Summary of risk management plan for Hydromorphone hydrochloride Kalceks (hydromorphone hydrochloride)

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

Summary of product characteristics (SPC) of **Hydromorphone hydrochloride Kalceks** and its package leaflet give essential information to healthcare professionals and patients on how **Hydromorphone hydrochloride Kalceks** should be used.

I. The medicine and what it is used for

Hydromorphone hydrochloride Kalceks is authorised for treatment of severe pain (see SPC for the full indication). It contains hydromorphone hydrochloride as the active substance and it is administered as injection or infusion; each 1 ml ampoule of solution for injection/infusion may contain 2 mg, 10 mg, 20 mg, or 50 mg hydromorphone hydrochloride and 10 ml ampoule contains 100 mg hydromorphone hydrochloride.

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

Important risks of **Hydromorphone hydrochloride Kalceks**, together with measures to minimise such risks and the proposed studies for learning more about risks of **Hydromorphone hydrochloride 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.

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

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

Important risks of **Hydromorphone hydrochloride 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 **Hydromorphone hydrochloride 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).

Important identified risks	Respiratory depression Physical and phychological dependence
Important potential risks	Drug abuse
Missing information	Use in pregnancy

II.B *Summary of important risks*

Table 3 Important identified risk - Respiratory depression

Important identified risk - Respiratory depression	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.3, 4.4, 4.6, 4.8, 4.9 and 5.1; PIL part 2, 3 and 4. Medicinal product subject to restricted medical prescription Additional risk minimisation measures Not applicable

Table 4 Important identified risk - Physical and phychological dependence

Important identified risk - Physical and phychological dependence	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4 and 4.8; PIL part 2 and 4. Medicinal product subject to restricted medical prescription Additional risk minimisation measures Not applicable

Table 5 Important potential risk – Drug abuse

Important potential risk – Drug abuse	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4; PIL part 2. Medicinal product subject to restricted medical prescription Additional risk minimisation measures Not applicable

Table 6 Missing information – Use in pregnancy

Missing information – Use in pregnancy	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.6; PIL part 2. Medicinal product subject to restricted medical prescription Additional risk minimisation measures Not applicable

II.C *Post-authorisation development plan*

Not applicable.