Part VI: Summary of the risk management plan

Summary of risk management plan for

Calcium folinate Kalceks 10 mg/ml solution for injection/infusion

(Calcium folinate)

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

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

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

I. The medicine and what it is used for

Calcium folinate Kalceks is authorised for to diminish the toxicity and counteract the action of folic acid antagonists such as methotrexate in cytotoxic therapy and overdose in adults and children. In cytotoxic therapy, this procedure is commonly known as "calcium folinate rescue". In combination with 5-fluorouracil in cytotoxic therapy. It contains calcium folinate as the active substance in concentration of 10 mg per 1 milliliter.

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

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

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

There are no studies required for Calcium folinate Kalceks.