Part VI: Summary of the risk management plan

Summary of risk management plan for
Palonosetron Kalceks 0.05 mg/ml solution for injection
(palonosetron hydrochloride)

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

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

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

I. The medicine and what it is used for

Palonosetron Kalceks 0.05 mg/ml solution for injection is authorised for the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults and paediatric patients 1 month of age and older. It contains palonosetron hydrochloride as the active substance and it is given by intravenous route of administration in concentration of 0.05 mg per millilitre.

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

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

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

II.A List of important risks and missing information

Important risks of Palonosetron 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 Palonosetron 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	*Severe Constipation* *Severe Hypersensitivity reactions*
Important potential risks	*QT/QTc prolongation* *Convulsive events* *Serotonin syndrome*
Missing information	*Effect in pregnancy* *Effect in lactating women* *Effects on fertility* *Effect in children aged less than 1 month (potential off-label use for CINV prevention)* *Effects in patients with end stage renal disease undergoing haemodialysis*

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 Palonosetron Kalceks.

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

There are no studies required for Palonosetron Kalceks.