Summary of risk management plan for

Ondansetron Kalceks 2 mg/ml solution for injection/infusion

(ondansetron)

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

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

I. The medicine and what it is used for

Ondansetron Kalceks 500 mg/ml solution for injection/infusion is authorised for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy and for the prevention and treatment of post-operative nausea and vomiting in adults and children. It contains ondansetron as the active substance and it is given by intravenous or intramuscular route of administration in concentration of 2 mg per millilitre.

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

Important risks of Ondansetron Kalceks, together with measures to minimise such risks and the proposed studies for learning more about risks of Ondansetron 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 Ondansetron Kalceks in not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Ondansetron 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 Ondansetron 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	*Hypersensitivity* *QT interval prolongation and Torsade de Pointes* *Profound hypotension and loss of consciousness when administered with apomorphine hydrochloride* *Toxic skin eruption, including Toxic Epidermal Necrolysis (TEN)*
Important potential risks	*Serotonin syndrome* *Adverse birth outcome following use during pregnancy* *Reduced clearance and prolonged half-life in patients with hepatic impairment* *Sub-acute intestinal obstruction in patients with impaired gastrointestinal motility* *Adverse events in breast-fed infants due to use of ondansetron during lactation*
Missing information	*Safety in pregnant women*

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 Ondansetron Kalceks.

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

There are no studies required for Ondansetron Kalceks.