Part VI: Summary of the risk management plan

Summary of risk management plan for Ondansetron Kabi

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

Ondansetron Kabi SmPC and its PL give essential information to healthcare professionals and patients on how Ondansetron Kabi should be used.

Important new safety concerns or changes to the current ones will be included in updates of the Ondansetron Kabi RMP.

I. The medicine and what it is used for

Ondansetron is authorised for –

Adults:

Ondansetron Kabi is indicated for management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.

Ondansetron Kabi is also indicated for the prevention and treatment of post-operative nausea and vomiting (PONV).

Paediatric Population:

Ondansetron Kabi is indicated for the management of chemotherapy-induced nausea and vomiting (CINV) in children aged ≥6 months, and for prevention and treatment of PONV in children aged ≥1 month.

It contains ondansetron as active substance and is administered by intravenous route.

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

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC 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.
- Specific adverse drug reaction follow-up forms (Targeted follow-up questionnaires)

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment 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 Ondansetron Kabi are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered via infusion. 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 Kabi. 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).

List of important risks and missing information	
Important identified risks	• Profound hypotension and loss of consciousness when administered with apomorphine hydrochloride • Hypersensitivity • QT interval prolongation and Torsade de Pointes • Toxic epidermal necrolysis (TEN)
Important potential risks	• Serotonin syndrome • Adverse birth outcomes 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 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 Kabi.

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

There are no on-going or closed studies for Ondansetron Kabi**.**