Part VI: Summary of the risk management plan

Summary of risk management plan for Ondansetron EQL Pharma

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

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

I. The medicine and what it is used for

Ondansetron EQL Pharma is authorised for prophylaxis and treatment of nausea and vomiting in adults, induced by cytotoxic chemotherapy and radiotherapy. Prophylaxis and treatment of post-operative nausea and vomiting induced by chemotherapy in adults and paediatric population (in children aged ≥ 6 months). Prophylaxis and treatment of post-operative nausea and vomiting in adults and children aged ≥1 month (see SmPC for the full indication). It contains ondansetron as the active substance, and it is given by oral route of administration.

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

Important risks of Ondansetron EQL Pharma, together with measures to minimise such risks and the proposed studies for learning more about Ondansetron EQL Pharma's risks, 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 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.

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 EQL Pharma is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Ondansetron EQL Pharma 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 EQL Pharma. 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 hypertension and loss of consciousness when administered with apomorphine hydrochloride • Hypersensitivity • QT prolongation and Torsade de Pointes • Toxic skin eruption, including 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 medicinal 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 EQL Pharma.

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

There are no studies required for Ondansetron EQL Pharma.