Part VI: Summary of the risk management plan

Summary of risk management plan for Ondansetron 4 mg and 8 mg solution for injection/infusion in pre-filled syringe

This is a summary of the risk management plan (RMP) for Ondansetron 4 mg and 8 mg solution for injection/infusion in pre-filled syringe. The RMP details important risks of Ondansetron 4 mg and 8 mg solution for injection/infusion in pre-filled syringe, how these risks can be minimised, and how more information will be obtained about Ondansetron 4 mg and 8 mg solution for injection/infusion in pre-filled syringe's risks and uncertainties (missing information).

Ondansetron 4 mg & 8 mg solution for injection/infusion in pre-filled syringe's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ondansetron 4 mg & 8 mg solution for injection/infusion in pre-filled syringe should be used.

Important new concerns or changes to the current ones will be included in updates of Ondansetron 4 mg & 8 mg solution for injection/infusion in pre-filled syringe RMP.

I. The medicine and what it is used for

Ondansetron 4 mg & 8 mg solution for injection/infusion in pre-filled syringe is indicated for

Adults:

Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, Prevention and treatment of post-operative nausea and vomiting (PONV).

Paediatric Population:

Management of chemotherapy-induced nausea and vomiting in children aged ≥6 months.

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

Important risks of Ondansetron 4 mg & 8 mg solution for injection/infusion in pre-filled syringe together with measures to minimise such risks and the proposed studies for learning more about Ondansetron 4 mg & 8 mg solution for injection/infusion in pre-filled syringe 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.

If important information that may affect the safe use of Ondansetron 4 mg & 8 mg solution for injection/infusion in pre-filled syringe is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Ondansetron 4 mg & 8 mg solution for injection/infusion in pre-filled syringe are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 4 mg & 8 mg solution for injection/infusion in pre-filled syringe. 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).

Important identified risk (s)	• 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 risk (s)	• 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 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 4 mg & 8 mg solution for injection/infusion in pre-filled syringe.

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

There are no studies required for Ondansetron 4 mg & 8 mg solution for injection/infusion in pre-filled syringe.