Summary of risk management plan for Metoclopramide Orion 10 Mg Film-Coated Tablets (Metoclopramide) Orion Corporation

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This is a summary of the risk management plan (RMP) for Metoclopramide Orion 10 Mg Film-Coated Tablets. The RMP details important risks of Metoclopramide Orion 10 Mg Film-Coated Tablets, how these risks can be minimised, and how more information will be obtained about Metoclopramide Orion 10 Mg Film-Coated Tablets risks and uncertainties (missing information).

Metoclopramide Orion 10 Mg Film-Coated Tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Metoclopramide Orion 10 Mg Film-Coated Tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Metoclopramide Orion 10 Mg Film-Coated Tablets RMP.

I. The medicine and what it is used for

Metoclopramide Orion is indicated in adults for prevention of delayed chemotherapy induced nausea and vomiting (CINV); prevention of radiotherapy induced nausea and vomiting (RINV); and symptomatic treatment of nausea and vomiting, including acute migraine induced nausea and vomiting.

Metoclopramide can be used in combination with oral analgesics to improve the absorption of analgesics in acute migraine. Metoclopramide Orion is indicated in children (aged 1-18 years) for prevention of delayed chemotherapy induced nausea and vomiting (CINV) as a second-line option. It contains metoclopramide as the active substance and it is given by mouth

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

Important risks of Metoclopramide Orion, together with measures to minimise such risks and the proposed studies for learning more about Metoclopramide Orion'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, 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

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.
The safety information in the product information is aligned to the reference medicinal product.

II.B Summary of important risks

The safety information in the product information is aligned to the reference medicinal product

II.C Post-authorisation development plan

There are no studies required for Metoclopramide Orion