Summary of risk management plan for Methylprednisolone Orion powder for solution for injection (methylprednisolone sodium succinate) Orion Corporation

Date: 8.5.2020, Version 3

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

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

Important new concerns or changes to the current ones will be included in updates of Methylprednisolone Orion's RMP.

I. The medicine and what it is used for

Methylprednisolone Orion is authorised for treatment of endocrinological diseases, rheumatologic diseases, collagen diseases, dermatological diseases, allergic conditions, ophthalmological diseases, gastrointestinal diseases, respiratory tract diseases, pneumocystis carinii pneumonia in AIDS patients, haematological diseases, neoplasms, renal diseases, neurological diseases, cardiovascular diseases, organ transplantation and certain other diseases (see SmPC for the full indication). It contains methylprednisolone as the active substance and it is given by intravenous or intramuscular injection or intravenous infusion.

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

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

II.B Summary of important risks

Safety concerns are adequately addressed in the product information.

II.C Post-authorisation development plan

There are no studies required for Methylprednisolone Orion