Summary of risk management plan for Hydrokortison Orion 10 mg Tablet (Hydrocortisone) Orion Corporation

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This is a summary of the risk management plan (RMP) for Hydrokortison Orion 10 mg Tablet. The RMP details important risks of Hydrokortison Orion 10 mg Tablet `how these risks can be minimised and and how more information will be obtained about Hydrokortison Orion 10 mg Tablet risks and uncertainties (missing information).

Hydrokortison Orion 10 mg Tablet summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Hydrokortison Orion 10 mg Tablet should be used.
Important new concerns or changes to the current ones will be included in updates of Hydrokortison Orion 10 mg Tablet RMP.

I. The medicine and what it is used for

Hydrokortison Orion is authorised for

- Replacement therapy in congenital adrenal hyperplasia in children.
- Treatment of adrenal insufficiency in children and adolescents < 18 years of age.
- Emergency treatment of severe bronchial asthma, drug hypersensitivity reactions, serum sickness, angioneurotic oedema and anaphylaxis in adults and children (see SmPC for the full indication).

It contains hydrocortisone as the active substance and it is taken by mouth.

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

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

Important risks of Hydrokortison Orion are risks that need special risk management activities to further

investigate or minimise the risk, so that the medicinal product can be safely <administered> <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 hydrocortisone. 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	• Steroid withdrawal syndrome
Important potential risks	• Phaeochromocytoma crisis • Cerebellar growth impairment • Teratogenicity
Missing information	None

II.B Summary of important risks

Safety concerns are adequately addressed in product information.

II.C Post-authorisation development plan

There are no studies required for Hydrokortison Orion.