Part VI: Summary of the risk management plan

Summary of risk management plan for

Hydrocortison Tiofarma 1, 2, 5, 10 and 20 mg, filmomhulde tabletten

This is a summary of the risk management plan (RMP) for Hydrocortison Tiofarma 1 mg, 2 mg, 5 mg, 10 mg and 20 mg filmomhulde tabletten. The RMP details important risks of hydrocortisone tablets, how these risks can be minimised, and how more information will be obtained about hydrocortisone's risks and uncertainties.

Hydrocortison Tiofarma 1 mg, 2 mg, 5 mg, 10 mg and 20 mg filmomhulde tabletten's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how the tablets should be used.

I. The medicine and what it is used for

Hydrocortison Tiofarma 1 mg, 2 mg, 5 mg, 10 mg and 20 mg filmomhulde tabletten are authorised for replacement therapy by adrenal insufficiency and therapy by medical emergencies (see SmPC for the full indication). It contains hydrocortisone as the active substance and it is given by oral administration as tablet in the strengths 1, 2, 5, 10 and 20 mg.

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

Important risks of Hydrocortison Tiofarma 1 mg, 2 mg, 5 mg, 10 mg and 20 mg filmomhulde tabletten, together with measures to minimise such risks and the proposed studies for learning more about Hydrocortison Tiofarma tablets' 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;
- 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 (Prescription only medicine) 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.

II.A List of important risks and missing information

Important risks of Hydrocortison Tiofarma 1 mg, 2 mg, 5 mg, 10 mg and 20 mg filmomhulde tabletten, 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 Hydrocortison Tiofarma 1 mg, 2 mg, 5 mg, 10 mg and 20 mg filmomhulde tabletten. 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	None
Important potential risks	None
Missing information	None

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 of the proposed products.

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

There are no studies required for the proposed products.