

## **PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN**

### **Summary of risk management plan for hydrocortisone tablets:**

Hydrocortisone belongs to a group of medicines called steroids. These corticosteroids occur naturally in the body and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as Hydrocortisone Tablets) is an effective way to treat various illnesses involving inflammation in the body. Corticosteroids mimic the

effects of hormones body produces naturally in adrenal glands that are located on top of each kidney. These hormones are essential for life.

This is a summary of the risk management plan (RMP) for hydrocortisone tablets. The RMP details important risks of hydrocortisone, how these risks can be minimised, and how more information will be obtained about hydrocortisone's risks and uncertainties (missing information). Hydrocortisone's summary of product characteristics (SmPC) gives essential information to healthcare professionals and patients on how hydrocortisone should be used. Important new concerns or changes to the current ones will be included in updates of hydrocortisone's RMP.

This summary of the RMP for hydrocortisone should be read in the context of all this information including

#### **I. The medicine and what it's used for:**

Hydrocortisone is used as replacement therapy in primary, secondary, or acute adrenocortical insufficiency.

It is also used pre-operatively, and during serious trauma or illness in patients with known adrenal insufficiency or doubtful adrenocortical reserve.

#### **II. Risks associated with the medicine and activities to minimize or further characterize the risks:**

Important risks of hydrocortisone, together with measures to minimize such risks and the proposed studies for learning more about hydrocortisone's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the summary of product characteristics (SmPC) addressed to patients and healthcare professionals.
- Important advice on the medicine's packaging.
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without Prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

**II.A. List of important risks and missing information**

Important risks of hydrocortisone are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered.

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is enough 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).

**Table 2: Summary of safety concerns**

<b>Important Identified Risks</b>
None
<b>Important Potential Risks</b>
None
<b>Missing Information</b>
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 or specific obligation of hydrocortisone.

## **II.C.2 Other Studies in Post Authorisation Development Plan**

There are no studies required for hydrocortisone.