Part VI: Summary of the risk management plan

Summary of risk management plan for SOFACOR (hydrocortisone)

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

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

I. The medicine and what it is used for

SOFACOR is authorised for the treatment of mild allergic or inflammatory conjunctival diseases. It contains hydrocortisone as active substances and it is given by ocular route.

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

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

Measures to minimise the risks identified for medicinal products are:

- 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.

If important information that may affect the safe use of SOFACOR is not yet available, it is listed under "missing information" below.

II.A List of important risks and missing information

Important risks of SOFACOR are risks that need special risk management activities to further investigate or minimise 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 sufficient proof of a link with the use of SOFACOR. 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	• Corneal calcification (related to phosphates)
Important potential risks	• Steroid withdrawal syndrome • Hypothalamus-pituitary-adrenal (HPA) axis suppression • Phaeochromocytoma crisis
Missing information	• Use in pregnant or lactating women • Use in paediatric population

II.B Summary of important risks

Important identified risk – Corneal calcification (related to phosphates)	
Evidence for linking the risk to the medicine	The Committee for Medicinal Products for Human Use assessed the use of phosphate buffers in medicinal products given as eye drops and whether these can cause corneal calcification. Data support the plausibility of an association between use of phosphate-containing eye drops in some patients with severe corneal damage and the development of corneal calcification and opacity.
Risk factors and risk groups	Severe damage to the cornea.
Risk minimisation measures	<u>Routine risk minimisation measures:</u> • SmPC section 4.8 • PL section 4 • Prescription only medicine

Important potential risk – Steroid withdrawal syndrome	
Evidence for linking the risk to the medicine	Steroid withdrawal syndrome is a known adverse reaction for hydrocortisone systemic formulations. However, severe forms of steroid withdrawal have been also noticed with topical formulations.
Risk factors and risk groups	None
Risk minimisation measures	Routine risk minimisation measures: • Prescription only medicine

Important potential risk – Hypothalamus-pituitary-adrenal (HPA) axis suppression	
Evidence for linking the risk to the medicine	HPA axis suppression is a known adverse reaction for hydrocortisone systemic formulations. However, cases have been also reported in the literature with topical formulations.
Risk factors and risk groups	None
Risk minimisation measures	Routine risk minimisation measures: • Prescription only medicine

Important potential risk – Phaeochromocytoma crisis	
Evidence for linking the risk to the medicine	Phaeochromocytoma crisis is a known adverse reaction for hydrocortisone systemic formulations.
Risk factors and risk groups	None
Risk minimisation measures	Routine risk minimisation measures: • Prescription only medicine

Missing information – Use in pregnant or lactating women	
Risk minimisation measures	Routine risk minimisation measures: • SmPC section 4.6 • PL section 2 • Prescription only medicine

Missing information – Use in paediatric population	
Risk minimisation measures	Routine risk minimisation measures: • SmPC section 4.2, 4.4 • PL section 2, 3 • Prescription only medicine

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 SOFACOR.

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

There are no studies required for SOFACOR.