Part VI: Summary of the risk management plan

Summary of risk management plan for DEXAFREE (Dexamethasone sodium phosphate)

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

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

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

I. The medicine and what it is used for

DEXAFREE is authorised for treatment of non-infectious inflammatory conditions affecting the anterior segment of the eye (see SmPC for the full indication). It contains dexamethasone sodium phosphate as the active substance, and it is given by ophthalmic route.

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

Important risks of DEXAFREE, together with measures to minimise such risks and the proposed studies for learning more about DEXAFREE'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;
- The authorised pack size — the amount of medicine in a pack (i.e. number of single-dose containers in the box or volume of solution in the multi-dose containers is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the fact that DEXAFREE requires a prescription to be 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 DEXAFREE is not yet available, it is listed under "missing information" below.

II.A List of important risks and missing information

Important risks of DEXAFREE 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 DEXAFREE. 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

There is no important risk for DEXAFREE.

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 DEXAFREE.

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

There are no studies required for DEXAFREE.