

Part VI: Summary of the risk management plan

Summary of risk management plan for COXAFEN (bromfenac)

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

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

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

I. The medicine and what it is used for

COXAFEN is authorized to treat inflammation in the eye that can occur after an operation to remove a cataract. It contains bromfenac as the active substance and it is given by ocular route of administration.

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

Important risks of COXAFEN, together with measures to minimize such risks and the proposed studies for learning more about COXAFEN'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 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 COXAFEN is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of COXAFEN are risks that need special risk management activities to further investigate or minimize 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 COXAFEN. 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).

Summary of safety concerns	
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 or specific obligation of COXAFEN.

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

There are no studies required for COXAFEN.