Summary of risk management plan for Posiforlid 20 mg/g, eye ointment

This is a summary of the risk management plan (RMP) for Posiforlid 20 mg/g, eye ointment. The RMP details important risks of Posiforlid 20 mg/g, how these risks can be minimized, and how more information will be obtained about Posiforlid's risks and uncertainties (missing information).

Posiforlid's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Posiforlid 20 mg/g, eye ointment should be used. Important new concerns or changes to the current ones will be included in updates of Posiforlid's RMP.

I. The medicine and what it is used for

Posiforlid 20 mg/g eye ointment is authorized for the treatment of chronic inflammation of the lid margin (Blepharitis chronica) not requiring antibiotic treatment in adults and children (see SmPC for the full indication). It contains bibrocathol as the active substance and it is given topically to the eye.

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

Important risks of Posiforlid 20 mg/g, eye ointment, together with measures to minimize such risks and the proposed studies for learning more about Posiforlid'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;
- Important advice on the medicine's packaging;
- The authorized 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 minimize risks.

Together, these measures constitute routine risk minimisation measures.

II.A List of important risks and missing information

Important risks of Posiforlid 20 mg/g, eye ointment 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 Posiforlid 20 mg/g, eye ointment. 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 or specific obligation of Posiforlid 20 mg/g, eye ointment.

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

There are no studies required for Posiforlid 20 mg/g, eye ointment.