Part VI: Summary of the risk management plan

Summary of risk management plan for ZAMIDINE (hexamidine diisetionate)

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

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

I. The medicine and what it is used for

ZAMIDINE is authorised for the treatment of purulent bacterial conjunctivitis caused by susceptible microorganisms, keratoconjunctivitis caused by susceptible microorganisms, blepharitis caused by susceptible microorganisms, chronic tear duct infections caused by susceptible microorganisms, and as preoperative antiseptic for the conjunctival sacs (see SmPC for the full indication). It contains hexamidine diisetionate as the active substance 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 ZAMIDINE together with measures to minimise such risk and the proposed studies for learning more about ZAMIDINE'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 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 riks.

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*.

II.A List of important risks and missing information

Important risks of ZAMIDINE 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 ZAMIDINE. 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

Not applicable.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

None.

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

None

Part VII: Annexes

Table of contents

Annex 1 – EudraVigilance Interface

Annex 1 is not required to be submitted in eCTD; the electronic file is submitted in accordance to GVP Module V.

Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

Not applicable

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

Not applicable

Annex 4 - Specific adverse drug reaction follow-up forms

Not applicable

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

Not applicable

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

Not applicable

Annex 7 - Other supporting data (including referenced material)

Not applicable

Annex 8 – Summary of changes to the risk management plan over time

Version	Approval date Procedure	Change
1.0	**Approval date:** Not applicable **Procedure number:** BE/H/0340/001/DC	RMP creation
1.1	**Approval date:** Not applicable **Procedure number:** BE/H/0340/001/DC	Following assessment by competent authorities (D70), a statement that the safety information in the product information is aligned to the reference medicinal product was added in Part V (according to GVP V, rev 2).
1.2	**Approval date:** Not applicable **Procedure number:** BE/H/0340/001/DC	Following assessment by competent authorities (D120), the new wording of the indication in section 4.1 of the SmPC was reflected in Part I and VI of the RMP.