Reference:

Annex 2: HaRP (Harmonisation of RMP Project) - methodology of harmonising RMPs, CMDh/402/2019, June 2019

Part III: Pharmacovigilance Plan (Including post-authorisation safety studies)

III.1 Routine Pharmacovigilance activities

There are no other routine pharmacovigilance activities proposed beyond adverse reactions reporting and signal detection for Ketorolac trometamol.

III.2 Additional Pharmacovigilance activities

No additional risk management activities are required. So no post authorisation safety studies or additional pharmacovigilance activities are planned for this product.

III.3 Summary table of additional Pharmacovigilance activities

Not applicable.

Part IV: Plans for post-authorisation efficacy studies

Misom Labs does not have plans to conduct any post authorization efficacy studies.

Part V: Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)

Risk Minimisation Plan

The safety information in the proposed product information is aligned to the reference medicinal product.

V.1 Routine Risk minimisation measures

Not applicable

V.2 Additional Risk Minimisation Measures

Not applicable

V.3 Summary table of risk minimisation measures

Not applicable

Part VI: Summary of the risk management plan

Summary of risk management plan for Ketorolac trometamol 5 mg/ml eye drops, solution

This is a summary of the risk management plan (RMP) for Ketorolac trometamol 5 mg/ml eye drops, solution. The RMP details important risks of Ketorolac trometamol, 5 mg/ml eye drops, solution, how these risks can be minimised and how more information will be obtained about Ketorolac trometamol 5 mg/ml eye drops, solution's risks and uncertainties (missing information).

Ketorolac trometamol 5 mg/ml eye drops, solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ketorolac should be used.

Important new concerns or changes to the current ones will be included in updates of Ketorolac trometamol 5 mg/ml eye drops, solution's RMP.

I. The medicine and what it is used for

Ketorolac trometamol 5 mg/ml eye drops, solution is indicated for Prophylaxis and reduction of inflammation following cataract surgery.

Ketorolac trometamol 5 mg/ml eye drops, solution contains Ketorolac trometamol as the active substance and it is given by ocular route of administration.

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

Important risks of Ketorolac, together with measures to minimise such risks and the proposed studies for learning more about Ketorolac'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 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.

II.A List of important risks and missing information

Important risks of Ketorolac 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 Ketorolac trometamol 5 mg/ml eye