Part VI: Summary of the risk management plan:

Summary of risk management plan for Novain 0.4% Eye Drops (Oxybuprocaine Hydrochloride)

This is a summary of the risk management plan (RMP) for Novain 0.4% Eye Drops. The RMP details important risks of Novain 0.4% Eye Drops, how these risks can be minimised, and how more information will be obtained about Novain 0.4% Eye Drops risks and uncertainties (missing information).

Novain 0.4% Eye Drops summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Novain 0.4% Eye Drops should be used.

I. The medicine and what it is used for

Novain 0.4% Eye Drops is authorised for Short-term local anaesthesia of the eye surface during:

- tonometry

- contact lens exams
- removal of foreign bodies from the surface of the eye

Novain 0.4% Eye Drops are administered to adults only. Since no data are available on the use of Novain 0.4% Eye Drops in children and adolescents, Novain is not recommended for use in these age groups.

It contains oxybuprocaine hydrochloride as the active substance and it is given by Ophthalmic/ Ocular route as sterile eye drop solution of 0.4% w/v.

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

Important risks of Novain 0.4% Eye Drops, together with measures to minimise such risks and the proposed studies for learning more about Novain 0.4% Eye Drops 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 analyzed 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 Novain 0.4% Eye Drops 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 Novain 0.4% Eye Drops. 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.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Important 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 authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of Novain 0.4% Eye Drops.

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

There are no studies required for Novain 0.4% Eye Drops.

Part VII: Annexes

Annex 6: SmPC and PIL of Novain 0.4% Eye Drops.

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