Summary of the risk management plan

Summary of risk management plan for OPHTESIC 20 mg/g, eye gel in a single dose container (lidocaine)

This is a summary of the risk management plan (RMP) for OPHTESIC 20 mg/g, eye gel in a Single dose container. The RMP details important risks of OPHTESIC 20 mg/g, eye gel in a Single dose container, how these risks can be minimised, and how more information will be obtained about OPHTESIC 20 mg/g, eye gel 's risks and uncertainties (missing information).

OPHTESIC 20 mg/g, eye gel 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how OPHTESIC 20 mg/g, eye gel should be used.

I. The medicine and what it is used for

OPHTESIC 20 mg/g, eye gel in a single dose container is authorised for Topical anaesthesia during ophthalmic procedures. It contains lidocaine as the active substance and it is given by local ocular application.

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

Important risks of OPHTESIC 20 mg/g, eye gel, together with measures to minimise such risks and the proposed studies for learning more about OPHTESIC 20 mg/g, eye gel's risks, are outlined below.

Measures to mjnimise 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 js 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 pharmacovigi/ance activities.

11.A List of important risks and missing information

Important risks of OPHTESIC 20 mg/g, eye gel 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 OPHTESIC 20 mg/g, eye gel. 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 longterm use of the medicine);

List of important risks and missing information	
Important identified risks	None
Important potential risks	Hypersensivity reactions
Missing information	None

11.B Summary of important risks

Important potential risk: Hypersensitivity reactions	
Evidence for linking the risk to the medicine	These reactions are described in literature data and in SmPCs of products containing lidocaine and other amide type anaesthetics.
Risk factors and risk groups	Patients who have known history of hypersensitivity reactions with any other amide type anaesthetic.
Risk minimisation measures	Routine risk minimisation measures Routine risk communication: SmPC section 4.3 PL section 2 Additional risk minimisation measures none

11.C Post-authorisation development plan

Not applicable.