Part VI: Summary of the risk management plan

Summary of risk management plan for Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution (Bimatoprost)

This is a summary of the risk management plan (RMP) for Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution. The RMP details important risks of Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution, how these risks can be minimised, and how more information will be obtained about Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution's risks and uncertainties (missing information).

Bimatoprost 0.1 mg/ml and 0.3 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 Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution should be used.

Important new concerns or changes to the current ones will be included in updates of Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution's RMP.

I. The medicine and what it is used for

Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers).

It contains bimatoprost as the active substance and given by ocular route.

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

Important risks of Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution together with measures to minimise such risks and the proposed studies for learning more about Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution'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 during signal management activity, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution is not yet available, it is listed under 'missing information' below

II.A List of important risks and missing information

Important risks of Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution 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 Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution. 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).

Important identified risk (s)	• Iris pigmentation • Punctate keratitis • Benzalkonium chloride (BAC) - related corneal toxicity (preserved formulations only) • Acute asthma and asthmatic symptoms
Important potential risk (s)	• Reactivation of previous infective ocular disease • Cardiovascular events (angina, bradycardia, hypotension)

	• Choroidal effusion • Intraocular pressure (IOP) increased • Off-label use (cosmetic use for the purpose of stimulating eyelash growth)
Missing information	• Use during pregnancy and lactation • Paediatric use

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 Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution.

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

There are no studies required for Bimatoprost 0.1 mg/ml and 0.3 mg/ml Eye Drops, Solution.