Part VI: Summary of the risk management plan

Summary of risk management plan for Bimatoprost Pharmabide (Bimatoprost)

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

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

I. The medicine and what it is used for

Bimatoprost Pharmabide is authorised 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) (see SmPC for the full indication). It contains Bimatoprost as the active substance and it is given by topical application, eye drops.

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

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

If important information that may affect the safe use of Bimatoprost Pharmabide is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Bimatoprost Pharmabide 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 Pharmabide. 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	*Iris pigmentation* *Punctate keratitis* *BAK-related corneal toxicity* *Acute asthma and asthmatic symptoms (Asthma, exacerbation of asthma, and Dyspnoea)*
Important potential risks	*Reactivation of previous ineffective ocular disease* *Choroidal effusion* *Increase in intraocular pressure* *Cardiovascular events (Angina; Bradycardia; Hypotension)* *Off-label use (Cosmetic use for the stimulation of eyelash growth)*
Missing information	*Exposure in paediatric patients* *Exposure in pregnancy and lactation*

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 Pharmabide.

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

There are no studies required for Bimatoprost Pharmabide.