Part VI: Summary of the risk management plan

Summary of risk management plan for Bimatoprost 0.3 mg/ml + Timolol 5mg/ml eye drops, solution

This is a summary of the risk management plan (RMP) for Bimatoprost 0.3 mg/ml + Timolol 5mg/ml eye drops, solution. The RMP details any important risks of Bimatoprost 0.3 mg/ml + Timolol 5mg/ml eye drops, solution, how these risks can be minimised, and how more information will be obtained about Bimatoprost 0.3 mg/ml + Timolol 5mg/ml eye drops, solution's risks and uncertainties (missing information).

Bimatoprost 0.3 mg/ml + Timolol 5mg/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 0.3 mg/ml + Timolol 5mg/ml eye drops, solution should be used.

Important new concerns or changes to the current ones will be included in updates of Bimatoprost 0.3 mg/ml + Timolol 5mg/ml eye drops, solution's RMP.

I. The medicine and what it is used for

Bimatoprost 0.3 mg/ml + Timolol 5mg/ml eye drops, solution is authorised for the reduction of intraocular pressure in adult patients with open-angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

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

Any important risks of Bimatoprost 0.3 mg/ml + Timolol 5mg/ml eye drops, solution, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as contraindications, warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- 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 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 0.3 mg/ml + Timolol 5mg/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 can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of the medicinal product. 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)

Summary of safety concerns	
Important identified risks	Iris hyperpigmentation
	Punctate keratitis
	Acute asthma and asthmatic symptoms
	Bradycardia
	Cystoid macular edema
Important potential risks	Choroidal detachment
	Cardiovascular events (angina, hypotension, congestive heart failure)
Missing information	Exposure in paediatric patients
	Exposure in pregnancy and lactation

II.B Summary of important risks

No important risks that would need special risk management activities have been identified for Bimatoprost 0.3 mg/ml + Timolol 5mg/ml eye drops, solution.

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 0.3 mg/ml + Timolol 5mg/ml eye drops, solution.

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

There are no studies required for Bimatoprost 0.3 mg/ml + Timolol 5mg/ml eye drops, solution.