Summary of risk management plan for Latanoprost 50 mcg/ml eye drops, solution

This is a summary of the risk management plan (RMP) for Latanoprost 50 mcg/ml eye drops, solution. The RMP details any important risks of Latanoprost 50 mcg/ml eye drops, solution, how these risks can be minimised, and how more information will be obtained about Latanoprost 50 mcg/ml eye drops, solution, solution's risks and uncertainties (missing information).

Latanoprost 50 mcg/ml eye drops, solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how the medicine should be used.

Any important new safety concerns or changes to the current ones will be included in updates of Latanoprost 50 mcg/ml eye drops, solution's RMP.

I. The medicine and what it is used for

Latanoprost Blumont 50mcg/ml eye drops solution is authorized for:

Reduction of elevated intraocular pressure (IOP) in patients with open angle glaucoma and ocular hypertension in adults (including the elderly).

Reduction of elevated IOP in paediatric patients with elevated IOP and paediatric glaucoma.

It contains latanoprost as active ingredient and it is given for ocular use as eye drops solution.

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

Any important risks of Latanoprost Blumont 50mcg/ml eye drops solution, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for medicinal products include:

- 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 Latanoprost Blumont 50mcg/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 Latanoprost Blumont 50mcg/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 taken. 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	Conjunctival hyperaemia Eyelash and vellus hair changes Periorbital skin discolouration Iris hyperpigmentation Keratitis herpetic
Important potential risks	Cystoid macular oedema Aggravation of asthma
Missing information	Ocular tolerability in paediatric population Long term safety in paediatric population (including ocular developmental and neurodegenerative events, hyperpigmentation changes in the eye, and corneal/endothelial functions/corneal thickness) Limited information on drug interactions in adult and paediatric patients Use in pregnant and lactating women

II.B Summary of important risks

Module SVII is not applicable and there are neither additional risk minimisation activities nor additional pharmacovigilance activities.

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 Latanoprost Blumont 50mcg/ml eye drops solution.

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

There are no studies planned for Latanoprost Blumont 50mcg/ml eye drops solution.