Part VI: Summary of the risk management plan

Summary of risk management plan for LOMITRAV (Bimatoprost/Timolol)

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

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

I. The medicine and what it is used for

LOMITRAV eye drops, solution is indicated for the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

It contain Bimatoprost and Timolol as the active substances and it is given by ocular route of administration (eye drops).

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

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

If important information that may affect the safe use of LOMITRAV is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of LOMITRAV 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 LOMITRAV. 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
Important potential risks	- Cardiovascular events (angina, hypotension, atrial fibrillation/arrhythmias, congestive heart failure) - Choroidal detachment - Cystoid macular oedema - Drug interaction with calcium channel blockers, guanethidine, beta-adrenergic, blocking agents, para-sympathomimetcs, anti-arrhythmics, digitalis glycosides, mydriatic agents and CYP2D6 inhibitors
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 for LOMITRAV.

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

There are no studies required for LOMITRAV.