Summary of risk management plan for Binotino (bimatoprost, timolol)

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

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

I. The medicine and what it is used for

Binotino is authorised for 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 contains bimatoprost and timolol as the active substances and it is given by topical application as eye drops.

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

Important risks of Binotino, together with measures to minimise such risks and the proposed studies for learning more about Binotino'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 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 Binotino is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Binotino 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 Binotino. 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 hyperpigmentation • Punctate keratitis • Acute asthma and asthmatic symptoms • Bradycardia • Cystoid macular edema
Important potential risks	• Cardiovascular events (angina, hypotension, congestive heart failure) • Choroidal detachment
Missing information	• Exposure in pediatric 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/Timolol EQL Pharma.

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

There are no studies required for Bimatoprost/Timolol EQL Pharma.