Part VI: Summary of the risk management plan

Summary of risk management plan for MONOPROST (latanoprost)

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

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

I. The medicine and what it is used for

MONOPROST is authorised for the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension (see SmPC for the full indication). It contains latanoprost as active substance and it is given by ocular route.

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

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

II.A List of important risks and missing information

Important risks of MONOPROST 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 MONOPROST. 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 discoloration • Iris hyperpigmentation • Herpetic keratitis
Important potential risks	• Cystoid macular oedema • Aggravation of asthma
Missing information	• Use during pregnancy and breastfeeding • Long term safety in paediatric patients (including ocular developmental and neurodegenerative events, hyperpigmentation changes in the eye, and corneal endothelial function/corneal thickness) • Ocular tolerability in paediatric population • Limited information on drug interactions in adult and paediatric patients • Long-term ocular safety (due to the high concentration of macrogolglycerol hydroxystearate)

II.B Summary of important risks

The safety information in the product information is aligned to the reference product with an additional missing information included for this product.

Information regarding other safety concerns is presented in the summary of the risk management plan of the reference product, thus only information related to the additional missing information is presented below.

Missing Information – Long-term ocular safety (due to the high concentration of macrogolglycerol hydroxystearate)	
Risk minimisation measures	Routine risk minimisation measures: • SmPC section 4.4 • PL section 2 • Prescription only medicine Additional risk minimisation measures: None
Additional pharmacovigilance activities	None

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 MONOPROST.

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

There are no studies required for MONOPROST.