Part VI: Summary of the risk management plan

Summary of risk management plan for XALOF 50 micrograms/ml eye drops, solution in unit dose container (latanoprost)

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

XALOF 50 micrograms/ml eye drops summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how XALOF 50 micrograms/ml eye drops should be used.

Important new concerns or changes to the current ones will be included in updates of XALOF 50 micrograms/ml eye drops' RMP.

I. The medicine and what it is used for

XALOF 50 micrograms/ml eye drops is authorised for the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension and the reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma.

It contains latanoprost as the 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 XALOF 50 micrograms/ml eye drops, together with measures to minimise such risks and the proposed studies for learning more about XALOF 50 micrograms/ml eye drops' risks, are outlined below.

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

- Adequate information is communicated to patients and healthcare professionals through the following sections of the SmPC/PIL: "Undesirable effects", ''Overdose'', ''precautions for use'', ''warnings ''

- 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 XALOF 50 micrograms/ml eye drops is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of XALOF 50 micrograms/ml eye drops are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely used. 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 XALOF 50 micrograms/ml eye drops. 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 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 function/corneal thickness) Limited information on drug interactions in adult and paediatric patients Use in pregnant and lactating women

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product XALATAN 50 micrograms/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 XALOF 50 micrograms/ml eye drops.

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

There are no studies required for XALOF 50 micrograms/ml eye drops, solution in unit dose container.