Summary of Risk Management Plan for Xalatan® (latanoprost)

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

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

Important new concerns or changes to the current ones will be included in updates of Xalatan® RMP.

I. The Medicine and What it is Used For

Xalatan® is authorised for reduction of elevated IOP in patients with open angle glaucoma and ocular hypertension. Reduction of elevated IOP in paediatric patients with elevated IOP and paediatric glaucoma. It contains latanoprost as the active substance and it is given by as the recommended therapy is one eye drop in the affected eye(s) once daily. Optimal effect is obtained if latanoprost is administered in the evening. If one dose is missed, treatment should continue with the next dose as planned. The dose should not exceed one drop in the affected eye(s) daily. Further, 100 mL eye drops solution contains 0.005 g latanoprost. One drop contains approximately 1.5 µg latanoprost.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Xalatan, together with measures to minimise such 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 public (e.g., with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures. In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of Important Risks and Missing Information

Important risks of Xalatan® are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Xalatan. 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/use in special patient populations etc.);

Table 1: Part VI.1- Summary of safety concerns

Important Identified Risks	• None
Important Potential Risks	• None
Missing Information	• None

II.B Summary of Important Risk

Not Applicable.

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 Xalatan®.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Xalatan®