Part VI: Summary of the risk management plan

Summary of risk management plan for Latanoprost STADA 50 Mikrogramm/ml Augentropfen, Lösung im Einzeldosisbehältnis (Latanoprost)

This is a summary of the risk management plan (RMP) for Latanoprost STADA 50 micrograms/mL Eye drops, solution in single-dose container. The RMP details important risks of Latanoprost STADA 50 micrograms/mL Eye drops, solution in single-dose container, how these risks can be minimised, and how more information will be obtained about Latanoprost STADA's 50 micrograms/mL Eye drops, solution in single-dose container risks and uncertainties (missing information).

Latanoprost STADA 50 micrograms/mL Eye drops, solution in single-dose container's 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Latanoprost STADA 50 micrograms/mL Eye drops, solution in single-dose container should be used.

Important new concerns or changes to the current ones will be included in updates of Latanoprost STADA's 50 micrograms/mL Eye drops, solution in single-dose container RMP.

I. The medicine and what it is used for

Latanoprost STADA 50 micrograms/mL Eye drops, solution in single-dose container is authorised for Reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension (see SmPC for the full indication).

It contains Latanoprost as the active substance and it is administered by an ocular route of administration.

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

Important risks of Latanoprost STADA 50 micrograms/mL Eye drops, solution in single-dose container, together with measures to minimise such risks and the proposed studies for learning more about Latanoprost STADA's 50 micrograms/mL Eye drops, solution in single-dose container 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 Latanoprost STADA's 50 micrograms/mL Eye drops, solution in single-dose container is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Latanoprost STADA 50 micrograms/mL Eye drops, solution in single-dose container 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 Latanoprost STADA 50 micrograms/mL Eye drops, solution in single-dose container. 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	• None
Important potential risks	• Aggravation of asthma • Central corneal thickness
Missing information	• Ocular tolerability in paediatric population • Long-term safety in paediatric patients (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.

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 Latanoprost STADA 50 micrograms/mL Eye drops, solution in single-dose container.

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

There are no studies required for Latanoprost STADA 50 micrograms/mL Eye drops, solution in single-dose container.