Part VI: Summary of the risk management plan

Summary of Risk Management Plan for Vizilatan 50 mcg/ml eye drops, solution

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

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

I. The Medicine and What It is used for

Vizilatan 50 mcg/ml eye drops, solution is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension and 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 topical route of administration (intraocular).

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

Important risks of Vizilatan 50 mcg/ml eye drops, solution, together with measures to minimise such risks and the proposed studies for learning more about Vizilatan 50 mcg/ml eye drops, solution '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.

The important information that may affect the safe use of Vizilatan 50 mcg/ml eye drops, solution and is not yet available, is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Vizilatan 50 mcg/ml eye drops, solution 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 Vizilatan 50 mcg/ml eye drops, solution. 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

Important potential risk: Aggravation of asthma	
Evidence for linking the risk to the medicine	Latanoprost, in clinical doses, has not been found to have any significant pharmacological effect on the respiratory system. Nevertheless, some cases of exacerbation of asthma and/or dyspnoea were reported in post marketing experience. Since there is limited experience from patients with asthma, the risk shall continue to be part of routine pharmacovigilance monitoring, and asthmatic patients should therefore be treated with caution until there is sufficient experience.
Risk factors and risk groups	Patients with respiratory problems should be treated with caution until there is sufficient experience
Risk minimisation measures	Routine risk minimisation measures
Important potential risk: Central corneal thickness	
Evidence for linking the risk to the medicine	Conclusions of PSUSA procedure for latanoprost (products with paediatric indication) PSUSA/00001834/201804 (finalised on 31/10/2018)
Risk factors and risk groups	Not applicable
Risk minimisation measures	Routine risk minimisation measures
Missing information: Ocular tolerability in paediatric population	
Risk minimisation measures	Routine risk minimisation measures
Missing information: Long-term safety in paediatric patients (including ocular developmental and neurodegenerative events, hyperpigmentation changes in the eye, and corneal endothelial function/corneal thickness)	
Risk minimisation measures	Routine risk minimisation measures
Missing information: Limited information on drug interactions in adult and paediatric patients	
Risk minimisation measures	Routine risk minimisation measures
Missing information: Use in pregnant and lactating women	
Risk minimisation measures	Routine risk minimisation measures

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 Vizilatan 50 mcg/ml eye drops, solution.

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

There are no studies required for Vizilatan 50 mcg/ml eye drops, solution.