Part VI: Summary of the risk management plan

Summary of risk management plan for [LATANOPROST/TIMOLOL] 50 mcg/ml + 5 mg/ml, eye drops solution, preservative free.

This is a summary of the risk management plan (RMP) for [LATANOPROST/TIMOLOL] 50 mcg/ml + 5 mg/ml, eye drops solution, preservative free. The RMP details important risks of [Latanoprost/Timolol] 50 mcg/ml + 5 mg/ml, eye drops solution, preservative free., how these risks can be minimised, and how more information will be obtained about [Latanoprost/Timolol] 50 mcg/ml + 5 mg/ml, eye drops solution, preservative free and uncertainties (missing information).

[Latanoprost/Timolol] 50 mcg/ml + 5 mg/ml, eye drops solution, preservative free summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Latanoprost/Timolol] 50 mcg/ml + 5 mg/ml, eye drops solution, preservative free should be used.

I. The medicine and what it is used for

[Latanoprost/Timolol] 50 mcg/ml + 5 mg/ml, eye drops solution, preservative free is used to reduce the pressure in the eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within the eye, eventually affecting the eyesight.
The safety and efficacy of latanoprost and timolol in adult patients with elevated eye pressure is supported by more than 13 years of clinical experience.

Ocular hypertension is when the pressure in the eye is higher than normal. In open-angle glaucoma, the high pressure is caused by fluid being unable to drain out of the eye.
[Latanoprost/Timolol] 50 mcg/ml+5mg/ml eye drops solution, preservative free can only be obtained with a prescription.

When the pressure inside the eye rises, it causes damage to the retina (the light-sensitive membrane at the back of the eye) and to the optic nerve that sends signals from the eye to the brain. This can result in serious vision loss and even blindness. By lowering the pressure, [Latanoprost/Timolol] 50 mcg/ml+5mg/ml eye drops solution, preservative free reduces the risk of damaging these structures.

[Latanoprost/Timolol] 50 mcg/ml+5mg/ml eye drops solution, preservative free is a clear eye-drop solution. It contains two active substances: latanoprost (50 micrograms per millilitre) and timolol (5 milligrams per millilitre) which lower the pressure in the eye in different ways. Latanoprost is a prostaglandin analogue (a man-made copy of the natural substance prostaglandin) that works by increasing the drainage of fluid out of the eye. Timolol is a beta-blocker that works by reducing the production of fluid within the eye. The combination of the

two active substances has an additive effect, reducing the pressure inside the eye more than either medicine alone.

This medicine does not contain a preservative.

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

Important risks of [Latanoprost/Timolol] 50 mcg/ml+5mg/ml eye drops solution, preservative free together with measures to minimise such risks and the proposed studies for learning more about [Latanoprost/Timolol] 50 mcg/ml+5mg/ml eye drops solution, preservative free 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 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/Timolol] 50 mcg/ml+5mg/ml eye drops solution, preservative free is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of [Latanoprost/Timolol] 50 mcg/ml+5mg/ml eye drops solution, preservative free 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/Timolol] 50 mcg/ml+5mg/ml eye drops solution, preservative free. 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	• None
Important potential risks	• None
Missing information	• None

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/Timolol] 50 mcg/ml+5mg/ml eye drops solution, preservative free.

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

There are no studies required for [Latanoprost/Timolol] 50 mcg/ml+5mg/ml eye drops solution, preservative free.