Part VI: Summary of the risk management plan

Summary of risk management plan for Taptiqom and Tafluprost/Timolol Santen (tafluprost + timolol)

This is a summary of the risk management plan (RMP) for Taptiqom and Tafluprost/Timolol Santen. The RMP details important risks of Taptiqom and Tafluprost/Timolol Santen, how these risks can be minimised, and how more information will be obtained about risks and uncertainties (missing information) of Taptiqom and Tafluprost/Timolol Santen.

Summary of product characteristics (SmPC) and package leaflet of Taptiqom and Tafluprost/Timolol Santen give essential information to healthcare professionals and patients on how Taptiqom and Tafluprost/Timolol Santen should be used.

Important new concerns or changes to the current ones will be included in updates of the RMP of Taptiqom and Tafluprost/Timolol Santen.

I. The medicine and what it is used for

Taptiqom and Tafluprost/Timolol Santen both contain the identical amount of tafluprost and timolol as active substances and are both given by eye drops.

Taptiqom is authorised for reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical monotherapy with beta-blockers or prostaglandin analogues and require a combination therapy, and who would benefit from preservative free eye drops (see SmPC for the full indication).

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

Important risks of Taptiqom and Tafluprost/Timolol Santen, together with measures to minimise such risks and the proposed studies for learning more about the risks of Taptiqom and Tafluprost/Timolol Santen, 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*.

II.A List of important risks and missing information

Important risks of Taptiqom and Tafluprost/Timolol Santen 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 Taptiqom and Tafluprost/Timolol Santen. 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	None.
Missing information	None.

II.B Summary of important risks

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 Taptiqom or Tafluprost/Timolol Santen.

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

There are no studies required for Taptiqom or Tafluprost/Timolol Santen.