

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for PROSOPTIMA**

This is a summary of the risk management plan (RMP) for PROSOPTIMA.

The RMP details important risks of PROSOPTIMA how these risks can be minimised, and how more information will be obtained about PROSOPTIMA 's risks and uncertainties (missing information).

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

#### **I. The medicine and what it is used for**

PROSOPTIMA is indicated 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).

It contains Tafluprost and timolol as the active substances and it is given by ocular route of administration (eye drops, solution).

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

Important risks of PROSOPTIMA together with measures to minimise such risks and the proposed studies for learning more about PROSOPTIMA '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.

If important information that may affect the safe use of PROSOPTIMA is not yet available, it is listed under 'missing information' below.

## **II.A List of important risks and missing information**

Important risks of PROSOPTIMA are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 PROSOPTIMA. 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);

<b>List of important risks and missing information</b>		
Important risks	identified	None
Important risks	potential	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 for PROSOPTIMA.

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

There are no studies required for PROSOPTIMA.