

## Part VI: Summary of the risk management plan

### Summary of risk management plan for FIXOPOST (Latanoprost 50 µg/ml + timolol maleate 5 mg/ml)

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

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

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

FIXOPOST is authorised for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues (see SmPC for the full indication). It contains latanoprost and timolol maleate as active substances and it is given by ocular route.

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

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

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

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

Important risks of FIXOPOST 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 FIXOPOST. 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>Summary of safety concerns</b>	
Important identified risks	<ul style="list-style-type: none"> <li>• Conjunctival hyperaemia</li> <li>• Eyelash and vellus hair changes</li> <li>• Periorbital skin discoloration</li> <li>• Iris hyperpigmentation</li> <li>• Herpetic keratitis</li> <li>• Cystoid macular oedema</li> <li>• Aggravation of asthma</li> <li>• Bronchospasm</li> <li>• Bradycardia</li> </ul>
Important potential risks	None
Missing information	<ul style="list-style-type: none"> <li>• Use in paediatric patients</li> <li>• Drug interactions</li> <li>• Use in pregnant and lactating women</li> <li>• Long-term ocular safety (due to the high concentration of macroglycerol hydroxystearate)</li> </ul>

## **II.B Summary of important risks**

The safety information in the product information is aligned to the reference product with an additional missing information included for this product.

Information regarding other safety concerns is presented in the summary of the risk management plan of the reference product, thus only information related to the additional missing information is presented below.

<b>Missing information: Long-term ocular safety (due to the high concentration of macroglycerol hydroxystearate)</b>	
Risk minimisation measures	<p><u>Routine risk communication:</u></p> <ul style="list-style-type: none"> <li>• SmPC section 4.4</li> <li>• PL section 4</li> </ul> <p><u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u> None</p> <p><u>Other routine risk minimisation measures beyond the Product Information:</u></p> <ul style="list-style-type: none"> <li>• Legal status: Prescription only medicine</li> </ul>
Additional pharmacovigilance activities	None

## ***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 FIXOPOST.

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

There are no studies required for FIXOPOST.