Swiss Risk Management Plan (RMP) of FIXAPROST (Latanoprost 50 µg/ml + timolol maleate 5 mg/ml)

Medicinal product: FIXAPROST
Active substance(s): Latanoprost, Timolol
Marketing Authorisation Holder: THEA Pharma S.A.
RMP Version number: EU RMP Version number 5.1 and Switzerland-Specific Annex
Date: 20-Dec-2022

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.
The RMP summary of Fixaprost is a concise document and does not claim to be exhaustive.
As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of Fixaprost in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. THEA Pharma S.A. is fully responsible for the accuracy and correctness of the content of the published summary RMP of Fixaprost.

I. The medicine and what it is used for

FIXAPROST 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 FIXAPROST, together with measures to minimise such risks and the proposed studies for learning more about FIXAPROST'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 FIXAPROST is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of FIXAPROST 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 FIXAPROST. 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).

Swiss Summary of safety concerns	
Important identified risks	• Periorbital skin discoloration • Iris hyperpigmentation • Cystoid macular oedema
Important potential risks	None
Missing information	• Use in paediatric patients • Drug interactions • Use in pregnant and lactating women • Long-term ocular safety (due to the high concentration of macrogolglycerol hydroxystearate)

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.

Important identified risk: Periorbital skin discoloration	
Risk minimisation measure	Routine risk communication: • Information for health professionals: section "Undesirable effects" • Patient information: section "Possible side effects" Routine risk minimisation activities recommending specific clinical measures to address the risk: None Other routine risk minimisation measures beyond the Product Information: • Legal status: Prescription only medicine
Additional pharmacovigilance activities	None

Important identified risk: Iris hyperpigmentation	
Risk minimisation measures	Routine risk communication: • Information for health professionals: sections "Warnings and precautions" and "Undesirable effects" • Patient information section "Possible side effects" Routine risk minimisation activities recommending specific clinical measures to address the risk: None Other routine risk minimisation measures beyond the Product Information: • Legal status: Prescription only medicine
Additional pharmacovigilance activities	None

Important identified risk: Cystoid macular oedema	
Risk minimisation measures	Routine risk communication: • Information for health professionals: sections "Warnings and precautions" and "Undesirable effects" • Patient information : section "Possible side effects" Routine risk minimisation activities recommending specific clinical measures to address the risk: None Other routine risk minimisation measures beyond the Product Information: • Legal status: Prescription only medicine
Additional pharmacovigilance activities	None

Missing information: Use in paediatric patients	
Risk minimisation measures	Routine risk communication: • Information for health professionals: section "Dosage/Administration" • Patient information: section "What you need to know before you take/use Fixaprost" Routine risk minimisation activities recommending specific clinical measures to address the risk: None Other routine risk minimisation measures beyond the Product Information: • Legal status: Prescription only medicine
Additional pharmacovigilance activities	None

Missing information: Drug interactions	
Risk minimisation measures	Routine risk communication: • Information for health professionals: sections "Warnings and precautions" and "Interactions" • Patient information: section "What you need to know before you take/use Fixaprost" Routine risk minimisation activities recommending specific clinical measures to address the risk: None Other routine risk minimisation measures beyond the Product Information: • Legal status: Prescription only medicine
Additional pharmacovigilance activities	None

Missing information: Use in pregnant and lactating women	
Risk minimisation measures	Routine risk communication: • Information for health professionals: section "Pregnancy, lactation" • Patient information: section "Can Fixaprost be taken/used during pregnancy or breast-feeding?" Routine risk minimisation activities recommending specific clinical measures to address the risk: None Other routine risk minimisation measures beyond the Product Information: • Legal status: Prescription only medicine
Additional pharmacovigilance activities	None

Missing information: Long-term ocular safety (due to the high concentration of macrogolglycerol hydroxystearate)	
Risk minimisation measures	Routine risk communication: • Information for health professionals: section "Warnings and precautions" • Patient information : section "Possible side effects" Routine risk minimisation activities recommending specific clinical measures to address the risk: None Other routine risk minimisation measures beyond the Product Information: • Legal status: Prescription only medicine
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 FIXAPROST.

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

There are no studies required for FIXAPROST.