Part VI: Summary of the risk management plan

Summary of Risk Management Plan for Tanafra (latanoprost)

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

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

Important new concerns or changes to the current ones will be included in updates of Tanafra 's RMP.

I. The Medicine and What It is used for

Tanafra is indicated for the:

- Reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension.
- Reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma.

It contains latanoprost as an active substance and its pharmaceutical form is eye drops solution (ophthalmic route of administration).

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

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

II.A List of Important Risks and Missing Information

Important risks of Tanafra 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 Tanafra. 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	• Aggravation of asthma • Central corneal thickness
Missing information	• Ocular tolerability in paediatric population • Long-term safety in paediatric patients (including ocular developmental and neurodegenerative events, hyperpigmentation changes in the eye, and corneal endothelial function/corneal thickness) • Limited information on drug interactions in adult and paediatric patients • Use in pregnant and lactating women

II.B Summary of Important Risks

The safety information in the 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 Tanafra.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Tanafra.