Summary of risk management plan for Jokath (Travoprost 40 micrograms/mL + Timolol 5 mg/mL) preservative free eye drops, solution.

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

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

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

I. The medicine and what it is used for

Jokath is authorised in adults for the decrease of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.
It contains travoprost and timolol maleate as a fixed combination of active substances 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 Jokath, together with measures to minimise such 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.

II.A List of important risks and missing information

Important risks of Jokath 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 Jokath. 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

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 of Jokath.

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

There are no studies required for Jokath.

Summary of risk management plan for Galya (Travoprost 40 micrograms/mL + Timolol 5 mg/mL) preservative free eye drops, solution.

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

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

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

I. The medicine and what it is used for

Galya is authorised in adults for the decrease of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.
It contains travoprost and timolol maleate as a fixed combination of active substances 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 Galya, together with measures to minimise such 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.

II.A List of important risks and missing information

Important risks of Galya 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 Galya. 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

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 of Galya.

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

There are no studies required for Galya.