	Medivis S.p.A.
	Plegik 10 mg/ml Collirio, Soluzione
Module 1	Administrative Information and Prescribing Information
Module 1.8	EU-RISK MANAGEMENT PLAN

Part VI: Summary of the risk management plan

Summary of risk management plan for Plegik 10 mg/ml eye drops, solution (cyclopentolate hydrochloride)

This is a summary of the risk management plan (RMP) for Plegik 10 mg/ml eye drops, solution. The RMP details important risks of Plegik 10 mg/ml eye drops, solution, how these risks can be minimised, and how more information will be obtained about Plegik 10 mg/ml eye drops, solution risks and uncertainties (missing information).

Plegik 10 mg/ml eye drops, solution summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Plegik 10 mg/ml eye drops, solution should be used.

Important new concerns or changes to the current ones will be included in updates of Plegik 10 mg/ml eye drops, solution RMP.

I. The medicine and what it is used for

For diagnostic use: Plegik is indicated for ocular fundus examinations and refraction examinations. For therapeutic use: Plegik is used as a mydriatic in the treatment of iritis, iridocyclitis, choroiditis and uveitis.


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

Important risks of Plegik 10 mg/ml eye drops, solution, together with measures to minimize such risks and the proposed studies for learning more about Plegik 10 mg/ml eye drops, solution's risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

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In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 Plegik 10 mg/ml eye drops, solution is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Plegik 10 mg/ml eye drops, solution are risks that need special risk management activities to further investigate or minimize 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 Plegik 10 mg/ml eye drops, solution. 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);

Summary of safety concerns	
Important identified risks	<ul style="list-style-type: none"> - Systemic toxicity in paediatric patients due to systemic absorption; - Systemic adverse effects due to the anticholinergic action of cyclopentolate; - Interaction with alkaloids, antiglaucomatous and other antimuscarinic drugs.
Important potential risks	- None
Missing information	- Safety of use in pregnancy and breastfeeding.

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 authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Plegik 10 mg/ml eye drops, solution.

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

There are no studies required for Plegik 10 mg/ml eye drops, solution.