Swiss Risk Management Plan Summary

Bilaxten eye drops, solution® (Bilastine)

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Marketing authorization holder: A. Menarini GmbH, Switzerland
Bilaxten Augentropfen, Lösung - Bilaxten collyre en solution

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 Bilaxten eye drops, solution 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 Bilaxten eye drops, solution in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. A. Menarini GmbH is fully responsible for the accuracy and correctness of the content of the published summary RMP of Bilaxten eye drops, solution.

SUMMARY OF RISK MANAGEMENT PLAN FOR BILASTINE EYE DROPS SOLUTION

I. THE MEDICINE AND WHAT IT IS USED FOR

Bilastine eye drops solution is intended for the treatment of ocular signs and symptoms of seasonal and perennial allergic conjunctivitis in adults (see SmPCs for the full indication). It contains bilastine as the active substance and is given by eye drops, solution formulation.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of Bilastine eye drops solution, together with measures to minimise such risks and the proposed studies for learning more about Bilastine eye drops solution'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 Bilastine 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 Bilastine eye drops solution are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or taken. 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 Bilastine 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);

List of important risks and missing information	
Important Identified Risks	• None
Important Potential Risks	• None
Missing Information	• Use in pregnancy and breastfeeding • Use in children aged 2 to 18 years

II.B. Summary of important risks

Use in pregnancy and breastfeeding	
Risk minimisation measures	Routine risk minimisation measures - SmPC section 4.6 Fertility, pregnancy and lactation The PIL of the concerned product is in line with the information contained in the SmPC previously described. Such information is given in the following sections of the PIL: - PIL section 2 What you need to know before you use Pregnancy, breast feeding and fertility Additional risk minimisation measures: No risk minimisation measures

Use in children aged 2 to 18 years	
Risk minimisation measures	Routine risk minimisation measures - SmPC section 4.2 Posology and method of administration The PIL of the concerned product is in line with the information contained in the SmPC previously described. Such information is given in the following sections of the PIL: - PIL section 2 What you need to know before you use Children and adolescents Additional risk minimisation measures: No risk minimisation measures

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 Bilastine eye drops solution.

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

There are no studies required for Bilastine eye drops solution