Part VI: Summary of the risk management plan

Summary of risk management plan for Bilastina DOC 20 mg tablets (bilastine)

This is a summary of the risk management plan (RMP) for Bilastina DOC20 mg tablets. The RMP details important risks of Bilastine, how these risks can be minimised, and how more information will be obtained about Bilastine's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Bilastine is authorised for the symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Bilastine is indicated in adults and adolescents (12 years of age and over). It contains bilastine as the active substance and it is given by oral route of administration.

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

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

II.A List of important risks and missing information

Important risks of Bilastine are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely 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. 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. use in children below 6 years of age).

Bilastine was authorized in Spain on 18-Nov-2010 and the risks of the product are fully characterised, appropriately managed by routine risk minimisation measures and fully integrated into standard clinical practice. There are no need of additional pharmacovigilance activities and/or risk minimisation activities to further characterise the risks of the product or to collect missing information about its use. For these reasons, no risks or important missing information are listed in this RMP.

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product Bilaxten®.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

N.A. There are no studies which are conditions of the marketing authorisation or specific obligation of Bilastine.

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

There are no studies required for Bilastine.