13 Part VI: Summary of the risk management plan (RMP) – Desloratadine, 5 mg, Film-coated tablet and 0.5 mg/ 1 ml, Oral solution

This is a summary of the RMP for desloratadine 5 mg, film-coated tablet and 0.5 mg/ 1 ml, oral solution. The RMP details important risks of desloratadine film-coated tablet and oral solution, how these risks can be minimized, and how more information will be obtained about desloratadine film-coated tablet and oral solution risks and uncertainties (missing information).

Desloratadine film-coated tablet and oral solution's summaries of product characteristics (SmPCs) and its package leaflets (PLs) give essential information to healthcare professionals (HCPs) and patients on how desloratadine film-coated tablet and oral solution should be used.

Important new concerns or changes to the current ones will be included in updates of the desloratadine film-coated tablet and oral solution's RMP.

13.1 Part VI: I. The medicine and what it is used for

Desloratadine, 5 mg, Film-coated tablet

Desloratadine film coated tablets are indicated in adult and adolescent aged 12 years and older for the relief of symptoms associated with allergic rhinitis and urticaria

Desloratadine, 0.5 mg/1 ml Oral solution

Desloratadine oral solution is indicated in adults, adolescents and children over the age of 1 year for the relief of symptoms associated with allergic rhinitis and urticaria

It contains desloratadine as active substance and is given orally in the form of film-coated tablet (5 mg) and oral solution (0.5 mg/1 ml).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of desloratadine film-coated tablet and oral solution, together with measures to minimize such 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 PL and SmPC addressed to patients and HCPs;
- 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (PSUR) assessment (if applicable)

so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of desloratadine film-coated tablet and oral solution are risks that need special risk management activities to further investigate or minimize 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 desloratadine film-coated tablet and oral 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

13.2.2 Part VI – II.B: Summary of important risks

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

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 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 desloratadine film-coated tablet and oral solution.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for desloratadine film-coated tablet and oral solution.