PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Desloratadin Apofri 5 mg film-coated tablets, Desloratadin ABECE 5 mg film-coated tablets, Desloratadin Punkt 5 mg film-coated tablets and Desloratadin Evolan 5 mg film-coated tablets (Desloratadine)

This is a summary of the risk management plan (RMP) for Desloratadin Apofri 5 mg film-coated tablets, Desloratadin ABECE 5 mg film-coated tablets, Desloratadin Punkt 5 mg film-coated tablets and Desloratadin Evolan 5 mg film-coated tablets (hereafter referred as Desloratadine tablets). The RMP details important risks of Desloratadine tablets, how these risks can be minimised, and how more information will be obtained about Desloratadine tablet's risks and uncertainties (missing information).

Desloratadine tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Desloratadine tablets should be used.
Important new concerns or changes to the current ones will be included in updates of Desloratadine tablet's RMP.

I. The medicine and what it is used for

Desloratadine tablets is authorised for treatment in adults and adolescent 12 years and older for the relief of symptoms associated with allergic rhinitis and urticaria (see SmPC for the full indication). It contains desloratadine 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 Desloratadine tablets, together with measures to minimise such risks, are outlined below.
Measures to minimise the risks identified for a medicinal product 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 Desloratadine tablets are risks that need special 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 Desloratadine tablets. 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 Desloratadine tablets.

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

There are no studies required for Desloratadine tablets.