Summary of risk management plan for Aerius, Azomyr, and Neoclarityn (desloratadine)

This is a summary of the RMP for Aerius, Azomyr, and Neoclarityn. The RMP details important risks of Aerius, Azomyr, and Neoclarityn, how these risks can be minimised, and how more information will be obtained about Aerius, Azomyr, and Neoclarityn's risks and uncertainties (missing information).

Aerius, Azomyr, and Neoclarityn's SmPCs and its package leaflets give essential information to healthcare professionals and patients on how Aerius, Azomyr, and Neoclarityn should be used.

This summary of the RMP for Aerius, Azomyr, and Neoclarityn should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Aerius, Azomyr, and Neoclarityn's RMP.

I. The Medicine and What it is Used for

Aerius, Azomyr, and Neoclarityn are authorised for adults, adolescents and children over the age of 1 year for the relief of symptoms associated with allergic rhinitis and urticaria. They contain desloratadine as the active substance and they are given orally.

Further information about the evaluation of Aerius, Azomyr, and Neoclarityn's benefits can be found in Aerius, Azomyr, and Neoclarityn's EPAR, including in its plain-language summary, available on the EMA website, under the medicines' webpage:

https://www.ema.europa.eu/en/medicines/human/EPAR/aerius

https://www.ema.europa.eu/en/medicines/human/EPAR/azomyr

https://www.ema.europa.eu/en/medicines/human/EPAR/neoclarityn

II. Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Aerius, Azomyr, and Neoclarityn, together with measures to minimise such risks and the proposed studies for learning more about Aerius, Azomyr, and Neoclarityn'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*.

II.A List of Important Risks and Missing Information

Important risks of Aerius, Azomyr, and Neoclarityn 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 Aerius, Azomyr, and Neoclarityn. 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 II.A.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
* The important identified or potential risks included in prior versions of the RMP have been removed based the review of accumulating clinical data and the guidance in GVP module V (Rev 2), as per routine updates of the RMP during the life cycle of the product	

II.B Summary of Important Risks

The safety information in the proposed Prescribing Information is aligned to the reference medicinal product. There are no important identified risks, important potential risks, or missing information in this RMP.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation of Aerius, Azomyr, and Neoclarityn.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Aerius, Azomyr, and Neoclarityn.