

Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for [Azelaſtine/Fluticasone propionate] 137 micrograms/50 micrograms per actuation, naſal ſpray, ſuſpenſion

This is a ſummary of the risk management plan (RMP) for [Azelaſtine/Fluticasone propionate] 137 micrograms/50 micrograms per actuation, naſal ſpray, ſuſpenſion (hereinafter referred to as Azelaſtine/Fluticasone propionate). The RMP details important risks, how theſe risks can be miniſimised, and how more information will be obtained about product’s risks and uncertainties (miſſing information).

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

Important new concerns or changes to the current ones will be included in updates of Azelaſtine/Fluticasone propionate's RMP.

I. The Medicine and What It is uſed for

[Azelaſtine/Fluticasone propionate] 137 micrograms/50 micrograms per actuation, naſal ſpray, ſuſpenſion is authoriſed for relief of ſymptoms of moderate to ſevere ſeaſonal and perennial allergic rhinitis if monotherapy with either intranaſal antihistamine or glucocorticoid is not conſidered ſufficient (ſee SmPC for the full indication). It contains azelaſtine and fluticasone propionate as the active ſubſtances and it is adminiſtered intranaſally.

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

Important risks of Azelaſtine/Fluticasone propionate, together with measures to miniſimise ſuch risks and the propoſed ſtudies for learning more about the product's risks, if any, are outlined below.

Measures to miniſimise 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 miniſimise its risks.

Together, theſe measures conſtitute *routine risk miniſimisation* 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 AzelaStine/Fluticasone propionate are risks that need special risk 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 AzelaStine/Fluticasone propionate. 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 4: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	<ul style="list-style-type: none"> None
Important potential risks	<ul style="list-style-type: none"> None
Missing information	<ul style="list-style-type: none"> None

There are no safety concerns applicable for this EU RMP based on the requirement to present only the important identified or potential risks and missing information linked to further pharmacovigilance activities or additional risk minimization measures in the EU.

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 AzelaStine/Fluticasone propionate.

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

There are no studies required for AzelaStine/Fluticasone propionate.