13 Part VI: Summary of the risk management plan for Azelastine hydrochloride + Fluticasone propionate, 137 micrograms/50 micrograms per actuation, Nasal spray, Suspension

This is a summary of the RMP for azelastine hydrochloride + fluticasone propionate, 137 micrograms/50 micrograms per actuation, nasal spray, suspension. The RMP details important risks of azelastine hydrochloride + fluticasone propionate, nasal spray, suspension, how these risks can be minimized, and how more information will be obtained about the azelastine hydrochloride + fluticasone propionate, nasal spray, suspension's risks and uncertainties (missing information).

Azelastine hydrochloride + fluticasone propionate, nasal spray, suspension's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how the product should be used.

Important new concerns or changes to the current ones will be included in updates of the azelastine hydrochloride + fluticasone propionate, nasal spray, suspension's RMP.

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

Azelastine hydrochloride + fluticasone propionate, nasal spray, suspension is authorized 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.

It contains azelastine hydrochloride and fluticasone propionate as active substances and is administered via nasal route as nasal spray, suspension (137 micrograms/50 micrograms per actuation).

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

Important risks of azelastine hydrochloride + fluticasone propionate, nasal spray, suspension together with measures to minimize such risks and the proposed studies for learning more about azelastine hydrochloride + fluticasone propionate, nasal spray, suspension's 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 package leaflet and SmPC addressed to patients and healthcare professionals;
- 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, 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 azelastine hydrochloride + fluticasone propionate, nasal spray, suspension are risks that need special risk management activities to further investigate or minimize 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 hydrochloride + fluticasone propionate, nasal spray, suspension. 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

N/A

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 for azelastine hydrochloride + fluticasone propionate, nasal spray, suspension.

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

There are no studies required for azelastine hydrochloride + fluticasone propionate, nasal spray, suspension.