Part VI:
Summary of the risk management plan for Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray, Suspension (azelastine hydrochloride/fluticasone propionate)

This is a summary of the risk management plan (RMP) for Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray, Suspension. The RMP details important risks of Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray, how these risks can be minimised, and how more information will be obtained about Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray's risks and uncertainties (missing information).

Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray, Suspension should be used.

Important new concerns or changes to the current ones will be included in updates of Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray's RMP.

I. The medicine and what it is used for

Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray is authorised for relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis (see SmPC for the full indication).

It contains azelastine hydrochloride/fluticasone propionate as the active substances and it is given by nasal spray, suspension.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray, together with measures to minimise such risks and the proposed studies for learning more about Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray'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***.

If important information that may affect the safety use of Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray 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 Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray. 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	• Effects on nasal mucosa
Important potential risks	• Psychiatric and behavioural reactions • Cushing syndrome, Cushingoid features, adrenal suppression • Growth retardation in children and adolescents • Glaucoma, cataract • Concurrent use of CYP3A4 inhibitors • Use in patients with severe hepatic impairment
Missing information	• Use in pregnancy and lactation

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 Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray.

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

There are no studies required for Azelastin/Fluticason Orifarm 137 mikrogramm/50 mikrogramm pro Sprühstoß Nasenspray.