Part VI: Summary of the risk management plan

Summary of risk management plan for Fluticasonfuroat Substipharm 27,5 Mikrogramm/Sprühstoß Nasenspray, Suspension

(Fluticasone Furoate)

(AT/H/1283/001/DC)

This is a summary of the risk management plan (RMP) for Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension. The RMP details important risks of Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension, how these risks can be minimised, and how more information will be obtained about Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension's risks and uncertainties (missing information).

Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension should be used.

Important new concerns or changes to the current ones will be included in updates of Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension's RMP.

I. The medicine and what it is used for

Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension is authorised for the treatment of the symptoms of allergic rhinitis in adults, adolescents and children (6 years and over) (see SmPC for the full indication). It contains Fluticasone Furoate as the active substance and it is given by intranasal spray administration.

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

Important risks of Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension, together with measures to minimise such risks and the proposed studies for learning more about Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension'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 (with 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 safe use of Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension 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 Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, 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);

List of important risks and missing information	
Important identified risks	Headache Nasal Events (including: Epistaxis, nasal ulceration, nasal septum perforation and other nasal events) Hypersensitivity Cataracts & glaucoma
Important potential risks	Taste & Smell disorders Pyrexia Systemic corticosteroid effect: Adrenal suppression Systemic corticosteroid effect: Growth retardation. Psychiatric effects
Missing information	Use in pregnancy and lactation Off-label use (sinusitis and children < 6 years of age)

II.B Summary of important risks

The safety information in the proposed product information is aligned to the reference medicinal product Avamys 27.5 micrograms/spray, nasal spray suspension and routine risk minimisation activities are sufficient to manage the safety concerns of the 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 Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension.

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

There are no studies required for Fluticasonfuroat Substipharm 27.5 Mikrogramm/Sprühstoß Nasenspray, Suspension.