Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for FLUTICASONE FUROATE 27.5 mcg/Spray, nasal spray suspension

This is a summary of the risk management plan (RMP) for FLUTICASONE FUROATE 27.5 mcg/Spray, nasal spray suspension (hereinafter referred to as Fluticasone Furoate). The RMP details important risks of Fluticasone Furoate, how these risks can be minimised, and how more information will be obtained about Fluticasone Furoate's risks and uncertainties (missing information).

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

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

I. The Medicine and What It is used for

Fluticasone Furoate 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 as nasal spray.

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

Important risks of Fluticasone Furoate, together with measures to minimise such risks and the proposed studies for learning more about Fluticasone Furoate's risks, if any, 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 (according to EURD list) 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 Fluticasone Furoate is not yet available, it is listed under ‘missing information’ below.

II.A List of Important Risks and Missing Information

Important risks of Fluticasone Furoate 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 Fluticasone Furoate. 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

Summary of safety concerns	
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 considered sufficient to ensure safe use of the 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 Fluticasone Furoate.

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

There are no studies required for Fluticasone Furoate.