PART VI SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT

Summary of risk management plan for Nasonex (mometasone furoate nasal spray)

This is a summary of the risk management plan (RMP) for Nasonex. The RMP details important risks of Nasonex, how these risks can be minimised, and how more information will be obtained about the risks and uncertainties of Nasonex (missing information).

The summary of product characteristics (SmPC) for Nasonex and its package leaflet give essential information to healthcare professionals and patients on how Nasonex should be used.

I. The medicine and what it is used for

Nasonex is authorised for use in adults and children 3 years of age and older to treat the symptoms of seasonal allergic or perennial rhinitis and for the treatment of nasal polyps in adults 18 years of age and older. It contains 50 micrograms of mometasone furoate as the active substance and it is given as sprays in each nostril.

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

Important risks of Nasonex, together with measures to minimise such risks and the proposed studies for learning more about the 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*.

II.A List of Important Risks and Missing Information

Important risks of Nasonex 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 Nasonex. 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 II.A.1: List of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks (Class effects) Possible systemic and local class effects of corticosteroids. Hypersensitivity reaction (Class effects) Possible systemic effects of corticosteroids at high doses may include psychological or behavioral disorders	• Adrenal suppression • Hypersensitivity reactions including anaphylactic reaction • Hyperglycaemia • Eye disorders (cataracts, glaucoma, increased intraocular pressure/ocular hypertension, chorioretinal disorder) • Nasal septum perforation • Psychological or behavioral disorders (psychomotor hyperactivity, sleep disorder, anxiety, depression, aggression [particularly in children])
Missing information	None

II.B Summary of Important Risks

Table II.B.1: Important Potential Risk: (Class Effect) Possible Systemic and Local Class Effects of Corticosteroids. Hypersensitivity Reaction

Evidence for linking the risk to the medicine	Mometasone furoate nasal spray post marketing data, literature
Risk factors and risk groups	Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal surgery, or trauma should not use a nasal corticosteroid until healing has occurred. Nasonex is not recommended in case of nasal septum perforation. Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Patients who are transferred from long-term administration of systemically active corticosteroids to NASONEX Nasal Spray require careful attention. Systemic corticosteroid withdrawal in such patients may result in adrenal insufficiency for a number of months until recovery of HPA axis function. If these patients exhibit signs and symptoms of adrenal insufficiency or symptoms of withdrawal (e.g., joint and/or muscular pain, lassitude, and depression initially) despite relief from nasal symptoms, systemic corticosteroid administration should be resumed and other modes of therapy and appropriate measures instituted. Such transfer may also unmask pre-existing allergic conditions, such as allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy. Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.
Risk minimisation measures	Routine risk minimisation measures

Table II.B.2: Important Potential Risk: (Class Effects) Possible Systemic Effects of Corticosteroids at High Doses May Include Psychological or Behavioral Disorders (Psychomotor Hyperactivity, Sleep Disorder, Anxiety, Depression or Aggression (Particularly in Children))

Evidence for linking the risk to the medicine	Mometasone furoate nasal spray post marketing data, literature
Risk factors and risk groups	Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations.
Risk minimisation measures	Routine risk minimisation measures

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 Nasonex.

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

There are no studies required for Nasonex.