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).

The important identified or potential risks included in prior versions of the RMP have been removed based the review of accumulating clinical data and the guidance in GVP module 5 (Rev 2), as per routine updates of the RMP during the life cycle of the product.

II.B Summary of Important Risks

Not Applicable

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.