Part VI: Summary of the risk management plan

Summary of risk management plan for MOMETASONE

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

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

I. The medicine and what it is used for

MOMETASONE is authorised for use in adults and children 3 years of age and older to treat the symptoms of seasonal allergic or perennial rhinitis. Furthermore MOMETASONE is authorised for the treatment of nasal polyps in adults 18 years of age and older (see SmPC for the full indication). It contains mometasone furoate 50 micrograms/actuation as the active substance and it is given by nasal administration.

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

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

If important information that may affect the safe use of MOMETASONE is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of MOMETASONE 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 MOMETASONE. 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);

Summary of safety concerns	
Important identified risks	• Nasal septum perforation • Growth retardation in children receiving prolonged treatment • Ocular events (cataract, glaucoma, ocular hypertension) • Systemic effects of mometasone (psychiatric and behavioural events, hyperglycemia, adrenal suppression) • Hypersensitivity (including anaphylactic reaction)
Important potential risks	• Risk of infection when used in immunocompromised patients • Use of mometasone in the presence of infections
Missing information	• Use in patients aged < 3 years • 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 MOMETASONE.

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

There are no studies required for MOMETASONE