Part VI: Summary of the Risk Management Plan

Summary of risk management plan for mometasone furoate

This is a summary of the risk management plan (RMP) for Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension. The RMP details important risks of Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension, how these risks can be minimised, and how more information will be obtained about Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension risks and uncertainties (missing information).

Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension should be used.

I. The medicine and what it is used for

Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension is authorised for the following indications:

- Use in adults and children 3 years of age and older to treat the symptoms of seasonal allergic or perennial allergic rhinitis
- Treatment of nasal polyps in adults 18 years of age and older

(see SmPC for the full indication).

It contains mometasone furoate as the active substance and it is given by intranasal route of administration as nasal spray, suspension.

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

Important risks of Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension, together with measures to minimise such risks and the proposed studies for learning more about Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension 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 Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension is not yet available, it is listed under 'missing information' below.

II.A. List of important risks and missing information

Important risks of Aphiahsone 50 micrograms/actuation Nasal Spray, 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 Aphiahsone 50 micrograms/actuation Nasal Spray, 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	1. Nasal septum perforation 2. Growth retardation in children receiving prolonged treatment 3. Ocular events (cataract, glaucoma, ocular hypertension, central serous chorioretinopathy) 4. Systemic effects of mometasone (psychiatric and behavioural events, hyperglycemia, adrenal suppression) 5. Hypersensitivity (including anaphylactic reaction)
Important potential risks	1. Risk of infection when used in immunocompromised patients 2. Use of mometasone in the presence of infections
Missing information	1. Use in patients aged < 3 years 2. Use in pregnancy and lactation

II.B. Summary of important risk

The safety information in the 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 Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension.

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

There are no studies required for Aphiahsone 50 micrograms/actuation Nasal Spray, Suspension.