Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Mometasone Furoate 50 micrograms/actuation Nasal Spray, Suspension

Mometasone Furoate

PL 40546/0209

Aristo Pharma GmbH

LAY SUMMARY

Mometasone Furoate 50 micrograms/actuation Nasal Spray, Suspension
Mometasone Furoate

This is a summary of the Public Assessment Report (PAR) for Mometasone Furoate Nasal Spray. It explains how this product was assessed, and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Mometasone Furoate Nasal Spray in this lay summary for ease of reading.

This product has been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) for the United Kingdom. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 01 February 2024 (DK/H/3377/001/DC). This is known as the MR/DC Reliance Procedure.

This application was approved under Regulation 52B of the Human Medicines Regulation 2012, as amended (previously Article 10(3) of Directive 2001/83/EC, as amended).

For practical information about using Mometasone Furoate Nasal Spray, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Mometasone Furoate Nasal Spray and what is it used for?
This medicine contains mometasone furoate, one of a group of medicines called corticosteroids.

When mometasone furoate is sprayed into the nose, it can help to relieve inflammation (swelling and irritation of the nose), sneezing, itching and a blocked up or runny nose.

How does Mometasone Furoate Nasal Spray work?

Hayfever and perennial rhinitis
This medicine is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial rhinitis in adults and children aged 3 and over.

Hayfever, which occurs at certain times of the year, is an allergic reaction caused by breathing in pollen from trees, grasses, weeds and also moulds and fungal spores. Perennial rhinitis occurs throughout the year and symptoms can be caused by a sensitivity to a variety of things including house dust mite, animal hair (or dander), feathers and certain foods. This medicine reduces the swelling and irritation in your nose and thereby relieving sneezing, itching and a blocked-up or runny nose caused by hayfever or perennial rhinitis.

Nasal polyps
This medicine is used to treat nasal polyps in adults aged 18 and over.

Nasal polyps are small growths on the lining of the nose and usually affect both nostrils. The nasal spray reduces the inflammation in the nose, causing the polyps to gradually shrink, thereby relieving a blocked feeling in the nose which may affect breathing through the nose.

How is Mometasone Furoate Nasal Spray used?
The pharmaceutical form of this medicine is nasal spray, suspension and the route of administration is nasal (through the nostrils).

Do not use a larger dose or use the spray more often or for longer than the patient's doctor tells them to.

Treatment of Hayfever and Perennial Rhinitis
Use in adults and children aged 12 years and over

The usual dose is two sprays into each nostril once a day.
- Once the patient's symptoms are under control, their doctor may advise the patient to decrease the dose to one spray into each nostril once a day.
- If the patient does not start to feel any better, they should see their doctor and he or she may tell them to increase the dose; the maximum daily dose is four sprays into each nostril once a day.

Use in children aged 3 to 11 years
The usual dose is one spray into each nostril once daily.

In some patients, the nasal spray begins to relieve symptoms within 12 hours after the first dose; however full benefit of treatment may not be seen in the first two days. Therefore, the patient should continue regular use to achieve full benefit of treatment.

If the patient (adult or child) suffer badly from hayfever, their doctor may tell them to start using the nasal spray some days before the start of the pollen season, as this will help to prevent the patient's hayfever symptoms from occurring. At the end of the pollen season the patient's hayfever symptoms should get better and treatment may then not be needed.

Nasal Polyps
Use in adults over 18 years
The usual starting dose is two sprays into each nostril once daily.
- If symptoms are not controlled after 5 to 6 weeks, the dose may be increased to two sprays in each nostril twice daily. Once symptoms are under control, the patient's doctor may advise the patient to decrease their dose.
- If no improvement in symptoms is seen after 5 to 6 weeks of twice daily administration, the patient should contact their doctor.

Due to the high-level of detail in the usage instructions it is best to refer directly to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website, for information on how Mometasone Furoate Nasal Spray, suspension is used.

For further information on how Mometasone Furoate Nasal Spray is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Mometasone Furoate Nasal Spray have been shown in studies?
No additional studies were needed as Mometasone Furoate Nasal Spray, Suspension contains the same active substance as the reference medicine, and satisfactory data to justify the differences have been provided.

What are the possible side effects of Mometasone Furoate Nasal Spray, Suspension?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

As Mometasone Furoate Nasal Spray, Suspension is a hybrid medicine and is therapeutically equivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

Why was Mometasone Furoate Nasal Spray approved?
It was concluded that Mometasone Furoate Nasal Spray has been shown to be therapeutically equivalent to the reference medicine. Therefore, the MHRA decided that, as for the reference medicine, the benefits are greater than the risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Mometasone Furoate Nasal Spray?
As for all newly authorised medicines, a Risk Management Plan (RMP) has been developed for Mometasone Furoate Nasal Spray. The RMP details the important risks of Mometasone Furoate Nasal Spray, how these risks can be minimised, any uncertainties about Mometasone Furoate Nasal Spray (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Mometasone Furoate Nasal Spray, Suspension.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Mometasone Furoate Nasal Spray are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Mometasone Furoate Nasal Spray
A marketing authorisation was granted in United Kingdom on 24 June 2024.

The full PAR for Mometasone Furoate Nasal Spray follows this summary.

This summary was last updated in September 2024.

TABLE OF CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Mometasone Furoate 50 micrograms/actuation Nasal Spray, Suspension (PL 40546/0209) could be approved.

Mometasone Furoate Nasal Spray is indicated for use in adults and children 3 years of age and older to treat the symptoms of seasonal allergic or perennial rhinitis.

The active substance, mometasone furoate, is a topical glucocorticosteroid with local anti-inflammatory properties at doses that are not systemically active.

It is likely that much of the mechanism for the anti-allergic and anti-inflammatory effects of mometasone furoate lies in its ability to inhibit the release of mediators of allergic reactions. Mometasone furoate significantly inhibits the release of leukotrienes from leucocytes of allergic patients. In cell culture, mometasone furoate demonstrated high potency in inhibition of synthesis and release of IL-1, IL-5, IL-6 and TNFα; it is also a potent inhibitor of leukotriene production. In addition, it is an extremely potent inhibitor of the production of the Th2 cytokines, IL-4 and IL-5, from human CD4+ T-cells.

This product has been authorised by MHRA for the United Kingdom. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 01 February 2024 (DK/H/3377/001/DC).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted during the DC procedure, please refer to the Reference Member State (RMS) Public Assessment Report, available on the RMS regulatory agency website or on the Heads of Medicines Agencies website.

This application was approved under Regulation 52B of the Human Medicines Regulation 2012, as amended (previously Article 10(3) of Directive 2001/83/EC, as amended).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A marketing authorisation was granted on 24 June 2024.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

The MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS

The MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS

The MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

The SmPC, PIL and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**