13.2 Part VI.2 Elements for a Public Summary

13.2.1 Part VI.2.1 Overview of disease epidemiology

Seasonal allergic or perennial rhinitis:

Seasonal allergic rhinitis (AR) (allergic reaction caused by breathing in pollen from trees, grasses, weeds, fungus and spores) occurs at certain times of year.

Perennial rhinitis (caused by sensitivity to variety of things including house dust, some insects, animal hair, feathers and certain foods) occurs for an hour or more on most days throughout the year. [Mackay IS, 1998].

Prevalence (occurrence) of rhinitis in the International Study on Asthma and Allergies in Childhood varied between 0.8 and 14.9% in 6-7 year olds and between 1.4 and 39.7% in 13-14 year olds. Countries with a very low occurrence include Indonesia, Albania, Romania, Georgia and Greece. Countries with a very high occurrence include Australia, New Zealand and the United Kingdom. In adults, national surveys show occurrence of rhinitis between 5.9% (France) and 29% (United Kingdom) with a mean of 16%. Perennial rhinitis is probably more common in adults than children [WAOb, 2017].

13.2.2 Part VI.2.2 Summary of treatment benefits

Many clinical trials have been carried to test the effectiveness of mometasone furoate. These studies have shown that once-daily administration of mometasone furoate is well tolerated and is effective in treatment of seasonal AR in comparison to placebo (drug without any

therapeutic effect). Its action begin within 7 hours after the dose is given to the patient and as the dosing schedule of the medication once-daily, it is easy for use as well [Berlucchi M, 2010]. Use of mometasone furoate (40 mcg/day per nostril) nasal spray for 6 months following 3 weeks after adenoidectomy (surgical removal of adenoids (organ present behind nasal cavity which is a part of immune system of the body) significantly prevented regrowth and reduced nasal obstruction symptoms in the early period compared to intranasal saline spray [Yildirim YS, 2016].

13.2.3 Part VI.2.3 Unknowns relating to treatment benefits

Limited data is available on the efficacy of mometasone furoate nasal spray in pregnant women. The efficacy of mometasone furoate nasal spray has not been studied for use in the treatment of unilateral (affecting one nostril) polyps (abnormal growth of tissues in any part with blood vessels), polyps associated with cystic fibrosis (disease affecting lungs that passes from one generation to another), or polyps that completely block the nasal cavities (information not relevant for BE/H/0265/001/DC, DE/H/5115/001/DC).

13.2.4 Part VI.2.4 Summary of safety concerns

Table 13-5 Important identified risks

Risk	What is known	Preventability
Overdose	NL/H/3882/001/DC: The maximum daily dose of mometasone furoate for treatment of hay fever and perennial rhinitis in adults and children over 12 years old is four sprays into each nostril once a day. The recommended dose in this indication for children 3-11 years old is one spray into each nostril once a day. The maximum dose for treatment of nasal polyps in adults is two sprays into each nostril twice daily. BE/H/0265/001/DC: The recommended dose for treatment of allergic rhinitis in adults is two sprays into each nostril once a day. DE/H/5115/001/DC: The recommended dose for treatment of hay fever (seasonal allergic rhinitis) in adults is two sprays into each nostril once a day. If steroids (used to relieve swelling and inflammation by acting on immune system) are used for a long time or in large amounts they may, rarely, affect some of the	Patients should not use a larger dose or use the spray more often or for longer than the doctor tells to. Patients should not take a double dose to make up for a forgotten dose. Patients should inform the doctor if they accidentally use more than they were told. It is recommended that the height of children receiving long-term treatment with nasal corticosteroids is regularly monitored and if any changes are noted, their doctor should be notified (not applicable for BE/H/0265/001/DC, DE/H/5115/001/DC). If the product is used for allergic rhinitis, it does not offer symptomatic treatment of the attack, and regular intake for several days is required before the effects of the treatment can

Risk	What is known	Preventability
	hormones (chemical substance produced in the body that controls and regulates the activity of certain cells or organs). In children this may result in slowed growth and development (not applicable for BE/H/0265/001/DC, DE/H/5115/001/DC).	be assessed. Potential overdoses are preventable by avoiding erroneously administering repeated doses (due to no recognition of an *immediate* effect).
Effects related to the body as a whole (Systemic effects)	Mometasone may cause systemic adverse effects, especially if it is administered at high doses and extended periods of time, such as suppression of the adrenal gland (organ that produces hormones), Cushing syndrome (a disease caused by high concentrations of the hormone cortisol in the blood).	Patients should not use a larger dose or use the spray more often or for longer than the doctor tells to. Patients who are taking other corticosteroid medicines as well should inform their doctor about them.
Disorders of the eye (Ocular disorders)	Increase in pressure in the eye (glaucoma) and/or cataracts causing visual disturbances may occur at an unknown frequency in patients using mometasone furoate.	It is recommended that in case the patient experiences any itching, watering in the eye, then he/she should immediately contact his/her doctor.
Allergy (Hypersensitivity reactions)	Immediate hypersensitivity (allergic) reactions may occur after use of this product. These reactions may be severe. Patients should stop taking mometasone furoate and get immediate medical help if they experience symptoms such as: • swollen face, tongue or pharynx • trouble swallowing • hives • wheezing or trouble breathing	It is recommended not to prescribe mometasone furoate, if the patient is allergic to the same or to any of the ingredients in the medicine. A few people may find that once they discontinue oral or injected corticosteroids (class of drugs that reduce swelling) they may seem to develop other allergies, such as itchy, watering eyes or patches of red and itchy skin. If patients develop any of these effects, they should contact their doctor.
Damage to the partition in the nose which separates the nostrils (Nasal septum perforation)	Damage to the partition in the nose which separates the nostrils may occur at an unknown frequency in patients using mometasone furoate.	If the patient has a nose injury or had an operation on the nose, it is recommended not to use the spray until the injury has healed. In case of any other infection the patient should visit a doctor or a pharmacist as an untreated infection may further worsen it. If a patient suffers from sore nose and bleeds the medication

Risk	What is known	Preventability
		should be stopped and immediate medical help is recommended.

Table 13-6 Important potential risks

Risk	What is known
Disorders related to the mental and emotional state or behavior of a person (Psychological or behavioral disorders)	When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body. Rarely, a range of psychological or behavioral effects including psychomotor hyperactivity (feelings of extreme restlessness accompanied by an increase in body movements), sleep disorders, anxiety (a feeling of worry, nervousness, or unease about something with an uncertain outcome), depression (feeling sad or low) or aggression (feelings of anger resulting in violent behavior) may be seen with the use of mometasone furoate particularly in children (not applicable for BE/H/0265/001/DC, DE/H/5115/001/DC).
Infections	Sore nose or throat and upper respiratory tract (part of the respiratory system including the nose, nasal passages, and throat) infection are common side effects of mometasone furoate. Patients should not use mometasone furoate if they have an untreated infection in their nose. Use of mometasone furoate during an untreated infection in nose, such as herpes, can worsen the infection. Patients should wait until the infection is resolved before they start using the nasal spray. Patients should talk to their doctor or pharmacist before using mometasone furoate if they have or ever had tuberculosis (infectious disease associated with suppression of immune system) have infection of the nose or throat or any other infection or if they are on medication for several months or longer. Patients should talk to their doctor if their immune system is not functioning well (if they have difficulty in fighting infection) while they are using mometasone furoate, and they come into contact with anyone with measles or chickenpox (type of viral infections). Patients should avoid coming into contact with anyone who has these infections.

Table 13-7 Missing information

Risk	What is known
Use in treatment of one sided overgrowth of tissue from the surface	Patients should talk to their doctor or pharmacist before using mometasone furoate if they have cystic fibrosis.

Risk	What is known
of a body organ, or associated with a hereditary disorder affecting the exocrine glands or which completely obstructs the nasal space (Use in the treatment of unilateral polyps, polyps associated with cystic fibrosis, or polyps that completely obstruct the nasal cavities) (not applicable for BE/H/0265/001/DC, DE/H/5115/001/DC)	The safety and efficacy of mometasone furoate nasal spray has not been studied for use in cystic fibrosis patients.
Use during pregnancy and lactation	There is little or no information on the use of mometasone furoate in pregnant women. It is not known if mometasone furoate is found in breast milk. If patients are pregnant or breast-feeding, think they may be pregnant or are planning to have a baby, they should ask their doctor or pharmacist for advice before taking this medicine.

13.2.5 Part VI.2.5 Summary of additional risk minimization measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimizing them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimization measures.

The SmPC and the PL for mometasone furoate can be found in the mometasone furoate's EPAR page.

For procedure number BE/0265/001/DC: This medicine has the following additional risk minimization measures:

Table 13-8 Overdose

Risk minimization measures
Summary description of main additional risk minimization measures: Pharmacists' guide **Objective and rationale:** The additional risk minimization activities are meant to remind HCPs of the importance of recognizing the risk of overdose and the need to instruct patients on correct usage of mometasone furoate nasal spray suspension, identification of signs and symptoms they need to look out for and what action are needed to be taken.

Risk minimization measures
Proposed action: Pharmacists' guide The Pharmacists' guide includes the following safety messages regarding overdose that can be explained to the patient: • Use for a maximum duration of 14 days, after which a doctor should be consulted if the symptoms have not/have only partially improved or have become worse. • Maximum of 3 months of uninterrupted treatment without medical advice. • The need for regular intake of the medication for several days before the effects of the treatment can be assessed as this medicinal product does not provide immediate relief of the symptoms and the maximum effect only occurs after several days. Do not exceed the recommended number of sprays per administration or the administration frequency of once per day

Table 13-9 Systemic effects

Risk minimization measures
Summary description of main additional risk minimization measures: Pharmacists' guide **Objective and rationale:** The additional risk minimization activities are meant to remind HCPs of the importance of recognizing the risk of systemic effects and the need to instruct patients on correct usage of mometasone furoate nasal spray suspension, identification of signs and symptoms they need to look out for and what action are needed to be taken. **Proposed action:** Pharmacists' guide The Pharmacists' guide includes the following safety messages regarding systemic effects that can be explained to the patient: • The medicinal product is indicated for patients aged 18 years and older, partly due to a risk of reduced growth rate in children, therefore the growth curve should be monitored by a doctor.

Table 13-10 Nasal septum perforation

Risk minimization measures
Summary description of main additional risk minimization measures:

Risk minimization measures
Pharmacists' guide **Objective and rationale:** The additional risk minimization activities are meant to remind HCPs of the importance of recognizing the risk of nasal septum perforation and the need to instruct patients on correct usage of mometasone furoate nasal spray suspension, identification of signs and symptoms they need to look out for and what action are needed to be taken. **Proposed action:** <u>Pharmacists' guide</u> The Pharmacists' guide includes the following safety messages regarding nasal septum perforation that can be explained to the patient: • The correct administration technique for preventing local irritation and perforation of the nasal septum: namely aiming away from the nasal septum.

13.2.6 Part VI.2.6 Planned post authorization development plan

None

13.2.7 Part VI.2.7 Summary of changes to the Risk Management Plan over time

N/A (first submission)