

## Mometasone

# Summary of the risk management plan

Version 1.1

## VI.2 Elements for a Public Summary

### VI.2.1 Overview of disease epidemiology

#### Rhinitis

Allergic rhinitis is a chronic disease in the upper airways and it affects quality of life, it has impact on work/school performance and productivity economic burden. The condition is relatively common worldwide, especially among the young. Allergic rhinitis can occur at any age, but most patients develop the condition before the age of 30. Both males and females are equally affected, although there is a preponderance of younger male patients.

#### Nasal polyposis

Nasal polyposis is an adult disorder involving the mucous membrane inside the nose. The cause of nasal polyposis is not fully defined. The condition affects approximately 2-4% of the general population and nasal polyposis is found in about 20% in those with cystic fibrosis. The risk of having nasal polyposis increases with age (mean 42 years) and the condition is more frequently found in men.

### VI.2.2 Summary of treatment benefits

“Mometasone contains mometasone furoate, a group of medicines called corticosteroids. When tiny amounts of mometasone furoate are sprayed into the nose, it can help to relieve inflammation, sneezing, itching and blocked up or runny nose. MOMETASONE can be used in adults and children aged 6 and older to treat the symptoms of hay fever (also called seasonal allergic rhinitis) and perennial rhinitis. In addition the product can be used in adults aged 18 and over to treat nasal polyps.”

#### Rhinitis

Mometasone has been shown to be effective in the management of seasonal and perennial allergic rhinitis and in the prophylaxis of seasonal allergic rhinitis in adults and adolescents (aged 12 to 85 years) and children (aged 6 to 11 years). It has been shown that 200 µg once daily is the optimum dose of mometasone nasal spray for the treatment of seasonal allergic rhinitis in adult patients and 100 µg once daily is the most appropriate dosage in children.

#### Nasal polyposis

Mometasone administered by a nasal spray has also been shown to be effective for the treatment of nasal polyposis in patients 18 years and older. Symptoms of nasal polyposis as loss of sense of smell and runny nose are also improved during treatment with mometasone. Results indicate that treatment with mometasone improve quality of life, sleep and daily activities.

### VI.2.3 Unknowns relating to treatment benefits

Mometasone has not been studied for use in the treatment of one-sided polyps, polyps associated with cystic fibrosis (a multi-organ genetic disease, primarily affecting the lungs and digestive system), or polyps that completely obstruct the nasal cavities.

### VI.2.4 Summary of safety concerns

#### Important identified risks

Risk	What is known	Preventability
Overdose	It is known that systemic ex-	- Precautions and recom-

Risk	What is known	Preventability
	<p>posure to corticosteroids can result in adverse effects such as retardation of growth in children.</p> <p>This adverse effect is much less likely to occur when using nasal corticosteroids compared to oral corticosteroids, however the adverse effect is seen with nasal mometasone when the drug is used in high doses for prolonged periods in children.</p> <p>Higher than the recommended doses of the product can lead to condition in which the adrenal glands do not produce adequate amount of cortisol (adrenal insufficiency).</p>	<p>mendations in the product information.</p> <p>- The patient needs a prescription before the product can be bought.</p> <p>-If there is evidence that a higher than the recommended dose was used an additional systemic corticosteroid cover should be considered during periods of stress or surgery.</p>

#### Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Psychological and behavioral disorders	Prolong usage of corticosteroids in high doses may cause psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).
Ocular disorders	Intraocular corticosteroids may in rare cases to cause intraocular pressure (glaucoma), clouding o the lens inside the eye (cataract) and disorders of the vascular layer of the eye (chorioretinal disorder).
Hypersensitivity reactions	Rarely, immediate hypersensitivity reactions such as allergic reactions - anaphylaxis (bronchospasm and dyspnea) may occur.
Nasal septum perforation	Intranasal corticosteroids may cause in rare cases nasal septum perforation.
Pregnancy/lactation	<p>From studies in animals it is known that there is a potential risk of decreased fetal growth, reduced fetal survival, malformations and difficult labor using mometasone in pregnancy.</p> <p>It is not known whether mometasone is excreted into breast milk.</p>
Infections	Corticosteroids inhibit the immune system and may reduce the symptoms of infection including fever, which entails the risk of overlooking infections in persons treated with corticosteroids. Corticosteroids further reduce the organism's defence against infection.

### Missing information

Risk	What is known
Special target population (Cystic fibrosis patients)	The safety and efficacy of mometasone has not been studied for use in the treatment of polyps associated with cystic fibrosis. Nasal polyposis occurs in 20% of patients suffering from cystic fibrosis. Mometasone has been used for many years without safety issues related to the use in cystic fibrosis patients for which reason the safety concern is not alarming.

#### **VI.2.5 Summary of risk minimisation 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 minimising 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 minimisation measures.

This medicine has no additional risk minimisation measures.

#### **VI.2.6 Planned post authorisation development plan**

No post-authorisation safety or efficacy studies are ongoing or are planned to be conducted for mometasone.

#### **VI.2.7 Summary of changes to the Risk Management Plan over time**

Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
1.0	27-02-2014	Important identified risks: -Overdose  Important potential risks: -Psychological or behavioral disorders -Ocular disorders -Hypersensitivity reactions -Nasal septum perforation -Pregnancy/lactation -Infections  Missing information: -Special target population (Cystic fibrosis patients)	
1.1	15-05-2014	No changes from the previous version of the RMP	

