PART VI – SUMMARY OF ACTIVITIES IN THE RISK MANAGEMENT PLAN BY MEDICINAL PRODUCT

The scientific summary of the RMP written for the lay reader provided in the following includes key elements of the RMP with a specific focus on risk minimisation activities and includes important information on potential and identified risks as well as missing information.

"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 hayfever (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."

1.18 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.

1.19 Summary of existing efficacy data

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 administrated 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.

1.20 Summary of safety concerns

Tables 7 briefly describe the safety concerns for MOMETASONE.

Important identified and potential risks are described separately as well as missing information.

Important Identified Risks		
Safety concern	**What is known**	**Preventability**
Overdose	It is known that systemic exposure to corticosteroids can result in adverse effects such as retardation of growth in children. 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.	- Precautions and recommendations in the product information. - The patient needs a prescription before the product can be bought.
Important Potential Risks		
Pregnancy/lactation	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. It is not known whether mometasone is excreted into breast milk.	- Precautions and recommendations in the product information not to use the product during pregnancy and lactation period unless strictly indicated. - The patient needs a prescription before the product can be bought.
Medication error	The active drug substance mometasone is found in a suspension inside the nasal spray. There is a potential risk of sedimentation and that the active drug substance will settle out of the fluid and come to rest against the inside of the bottle. This can cause administration of a too low dose.	- Recommendations on how to use the product in the product information indicate that the bottle should be shaken before administration and if the spray pump has not been used for 14 days or longer - The patient needs to consult a doctor and be in contact with pharmacists to buy the product which ensure proper information on how to use the product. - Product complaints received by the applicant will be evaluated on an annual basis.
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	- Precautions and recommendations in the product information. - The patient needs a prescription before the product

	with corticosteroids. Corticosteroids further reduce the organism's defence against infection.	can be bought.
Missing Information		
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.	- The limitation is described in the product information. - The patient needs to consult a doctor to have a prescription before the product can be bought. It is assumed that the doctor is aware of this safety concern.

Table 7: Safety concerns for MOMETASONE.

1.21 Summary of risk minimisation activities by safety concern

No additional risk minimisation measures have been proposed for the safety concern.

1.22 Planned post-authorisation development plan

No post-authorisation studies are planned for MOMETASONE.

1.23 Summary of changes to the risk management plan over time

Table 8 provides a listing of all significant changes to the RMP.

Date	Version of RMP	Description of change(s)	Responsible person
14-12-2012	01	New document	

Table 8: Listing of all significant changes to the RMP for MOMETASONE.