VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

- **Seasonal or Perennial Allergic Rhinitis**

In general, perennial rhinitis predominates in South America, Asia, Africa and Australia. Perennial and seasonal rhinitis occur commonly in the U.S.A. and Japan. Seasonal rhinitis predominates in Europe[1].

V. Bauchau et al conducted a two-step, cross-sectional, population-based survey in Belgium, France, Germany, Italy, Spain, and the UK to measure the prevalence of allergic rhinitis among European adults and the proportion of undiagnosed subjects. The prevalence was highest in northern countries (*e.g.* UK and Belgium) and lowest in southern countries (*e.g.* Spain and Italy). In France, 49% of patients consulting for allergic rhinitis were classified as having persistent allergic rhinitis. The conclusion of the study was that allergic rhinitis is common in Western Europe, affecting more than one out of five adults[2].

- **Nasal Polyposis (NP)**

In the general population, the prevalence of NP is considered to be around 4%. In cadaveric studies, this prevalence has been shown to be as high as 40%. They predominantly affect adults and usually present in patients older than 20. They are uncommon in children under 10 and may be the presenting feature of cystic fibrosis. There is at least a 2:1 male to female preponderance. Up to a third of NP patients have asthma, whereas polyps are only found in 7% of asthmatics[3].

Comorbidities and risk factors

- **Seasonal or Perennial Allergic Rhinitis**

Major comorbidities in patients with allergic rhinitis include asthma, rhinosinusitis (RS), otitis media with effusion (OME), cognitive disorder and sleep disturbance[5].

- **Nasal Polyposis**

Medical conditions commonly associated with polyps include asthma, bronchiectasis, and cystic fibrosis. There is a well recognized subgroup of patients with Samnter's Triad comprising polyposis, asthma, and aspirin hypersensitivity which makes up almost 10% of cases of NP[3].

VI.2.2 Summary of treatment benefits

Current (gold) standards of treatment

Seasonal or Perennial Allergic Rhinitis Although allergen avoidance is the most cost-effective means of managing allergic rhinitis, treatment with pharmacologic agents represents the standard approach to seasonal or perennial allergic rhinitis. Oral antihistamines of H1 class are effective for nasopharyngeal itching, sneezing and watery rhinorrhea. Because antihistamines have little effect on congestion, alpha-adrenergic agents such as phenylephrine or oximetazoline are generally used. Intranasal high-potency glucocorticoids are the most potent drugs available for the relief of established rhinitis, seasonal or perennial and are effective in relieving nasal congestion. The currently available intranasal glucocorticoids- beclomethasone, fluticasone propionate, fluticasone furoate, ciclesonide and mometasone furoate are equally effective for nasal symptom relief including nasal congestion[6].

- **Nasal Polyposis**

Local corticosteroids have a documented effect on bilateral NP and also on symptoms associated with NP such as nasal blockage, secretion and sneezing. There is convincing evidence for a therapeutic effect on polyp size and nasal symptoms associated with nasal polyposis, particularly nasal blockage. Furthermore, the postoperative effect on the recurrence rate of NP with intranasal steroids is well documented. Topical steroids are therefore the first-choice treatment of NP[7].

VI.2.3 Unknowns relating to treatment benefits

Mometasone is not a new, but a well-established drug (more than 10 years in the market). The use is well established with recognised efficacy and acceptable safety.

VI.2.4 Summary of safety concerns

Important identified risks:

Risk	What is known	Preventability
Overdose	Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not use a larger dose or use the spray more often or for longer than your doctor tells you to. If you forget to use your nasal spray at the right time, use it as soon as you remember, then carry on as before. Do not take a double dose to make up for a forgotten dose. When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur very rarely due to the drug being absorbed in the body. Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function.	Administration according to the recommendations laid out in the SmPC and PIL

Important potential risks:

Risk	What is known
Psychological or behavioural disorders	Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in the leaflet.
Ocular disorders	Like all medicines, this medicine can cause side effects, although not everybody gets them. Most people do not have any problems after using the nasal spray. Increase in pressure in the eye (glaucoma) and/or formation of clouding of the lens in the eye (cataracts), causing visual disturbances and damage to the partition in the nose which separates the nostrils.

Hypersensitivity reactions	Like all medicines, this medicine can cause side effects, although not everybody gets them. Immediate hypersensitivity reactions, including bronchospasm and dyspnea are reported rarely.
Nasal septum perforation	Like all medicines, this medicine can cause side effects, although not everybody gets them. Damage to the partition in the nose which separates the nostrils has been reported rarely.
Pregnancy/lactation	If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Corticosteroids cross the placenta. Mometasone should not be used unless strictly indicated. It is not known whether mometasone is excreted into breast milk. Therefore the use of mometasone during breast-feeding is not recommended.
Infections	Do not use Mucomo If you have an infection in your nose. You should wait until the infection is resolved before you start using the nasal spray. Talk to your doctor or pharmacist before using Mucomo: If you have or have ever had tuberculosis or If you have an eye infection, caused by a virus called herpes simplex or If you have any other type of infection. While using Mucomo, avoid coming into contact with anyone who has measles or chickenpox. You should tell your doctor if you do come into contact with anyone who is suffering from these infections. Infections in the upper respiratory tract have been reported with the use of mometasone.

Missing information:

Risk	**What is known**
Special target population (cystic fibrosis patients)	The safety and efficacy of mometasone furoate has not been studied for use in the treatment of unilateral polyps, polyps associated with cystic fibrosis, or polyps that completely obstruct the nasal cavities. Talk to your doctor or pharmacist before using Mucomo: If you have cystic fibrosis (a multi-organ genetic disease, primarily affecting the lungs and digestive system).

VI.2.5 Summary of risk minimisation measures by safety concern

Mometasone SmPC 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 the SmPC and PL are routine risk minimisation measures. Mometasone has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

N/A

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

N/A