VI.2 Elements for a Public Summary

PRODUCT NAME 50 micrograms/actuation Nasal Spray, Suspension

VI.2.1 Overview of disease epidemiology

Seasonal allergic or perennial rhinitis

Allergic rhinitis (irritation and inflammation of the mucous membrane inside the nose) is caused by exposure to allergens and leads to sneezing, blocked or runny nose. It affects patients of all ethnicities and of all ages. It is estimated to affect 10% to 30% of children and adults. Incidence peaks in childhood and adolescence. Hayfever, which occurs at certain times of the year, is an allergic reaction caused by breathing in pollen from trees, grasses, weeds and also molds and fungal spores. Perennial rhinitis is a sub-form of allergic rhinitis that occurs throughout the year and not just seasonally. Symptoms of perennial rhinitis can be caused by a sensitivity to a variety of things including house dust mite, animal hair (or dander), feathers and certain foods. These allergies cause a runny nose and sneezing and make the lining of the nose swell, causing a stuffy blocked-up feeling. PRODUCT NAME reduces the swelling and irritation in your nose and so relieves sneezing, itching and a blocked-up or runny nose.

Nasal polyps

Nasal polyps are small growths on the lining of the nose (mucosa) and usually affect both nostrils. The main symptom is a blocked nose which may affect breathing. Watering from the nose, a feeling of something running down the back of the throat and loss of taste and smell may also occur. The prevalence of nasal polyps is estimated to be between 1% and 4% (1 to 4 patients out of 100). Incidence increases with age and is probably the greatest between 40 and 60 years of age. PRODUCT NAME reduces the inflammation in the nose, causing the polyps to gradually shrink.

VI.2.2 Summary of treatment benefits

PRODUCT NAME 50 micrograms/actuation Nasal Spray contains mometasone furoate, one of a group of medicines called corticosteroids. Mometasone furoate should not be confused with “anabolic” steroids misused by some athletes and taken as tablets or injections. When tiny amounts of mometasone furoate are sprayed into the nose, it can help to relieve inflammation, sneezing, itching and a blocked up or runny nose.

VI.2.3 Unknowns relating to treatment benefits

There are no or limited amount of data about the use of mometasone furoate in pregnant women.
The safety and efficacy of mometasone furoate in children under 3 years of age for the treatment of seasonal allergic rhinitis and perennial rhinitis have not been established, as well as for the treatment of nasal polyps in children and adolescents under 18 years of age.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
None	NA	NA

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Systemic corticosteroid effects	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. These side effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations.
Nasal septum perforation	In rare cases, treatment with corticosteroid nasal sprays like this medicine has led to damage to the partition in the nose which separates the nostrils
Increased pressure in the eye (Increased intraocular pressure)	In rare cases, treatment with corticosteroid nasal sprays like this medicine has led to an increase in eye pressure (glaucoma).
Psychological or behavioural disorders	Potential systemic effects of nasal corticosteroids may include psychological or behavioural effects including psychomotor hyperactivity.
Allergic reactions (Hypersensitivity reactions)	Rarely, immediate allergic reactions, including shortness of breath, may occur after intranasal administration of mometasone.

Missing information

Risk	What is known
Use during pregnancy	You should not use PRODUCT NAME if you are pregnant unless your doctor has told you to. Tell your doctor if you are pregnant before you start using this medicine. You should not breast feed when you are using this medicine unless your doctor has told you to.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) 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.

The Summary of Product Characteristics and the Package leaflet for PRODUCT NAME can be found in the PRODUCT NAME's EPAR page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies have been imposed or are planned.

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

Not applicable.