VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Allergic rhinitis (AR) is the most common chronic nasal inflammatory disorder that affects the upper respiratory airways. AR has traditionally been classified as **seasonal** (also called hay fever) or **perennial** (persistent AR). Hay fever, which occurs at certain times of the year, is an allergic reaction caused by breathing in pollen from trees, grasses, weeds and also moulds and fungal spores. Perennial rhinitis occurs throughout the year and symptoms 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. The World Health Organization has estimated that 400 million people in the world suffer from AR. It is estimated that AR affects 10% to 30% of adults, and nearly 40% children worldwide.

VI.2.2 Summary of treatment benefits

Based on the available data from clinical studies and clinical experience of several years, fluticasone nasal spray suspension represents an effective drug in the prophylaxis and treatment of seasonal allergic rhinitis (including hay fever) and perennial rhinitis in adults and children aged 4 years and older.

If administered as indicated in the Summary of Product Characteristics and taking into account the contraindications, the warnings and precautions, fluticasone nasal spray suspension can be considered effective in the approved indications and generally well tolerated.

VI.2.3 Unknowns relating to treatment benefits

There is limited information regarding fluticasone administration during human pregnancy. The secretion of fluticasone in human breast milk has not been investigated.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Systemic endocrine corticosteroid effects: Cushing's syndrome; Cushingoid features	Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features.	Treatment with nasal corticosteroids may affect the production of steroids in the body. The likelihood of such an incidence is increased by use of a high dose over a long period of time. Your doctor will help prevent this happening by prescribing the lowest dose of steroid capable of adequately controlling your symptoms.
Adrenal suppression and growth retardation in children and	Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral	Children may grow more slowly than others, and therefore children receiving treatment with nasal corticosteroids over a

Risk	What is known	Preventability
adolescents	corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include adrenal suppression, growth retardation in children and adolescents.	long period of time will have their height checked regularly by their doctor. Your doctor will help prevent this happening by prescribing the lowest dose of steroid capable of adequately controlling the symptoms.
Ocular events (cataract, glaucoma)	Side effects occurring very rarely: glaucoma (raised pressure in the eye) and cataracts (clouding of the lens in the eye) have been reported following prolonged treatment.	Some side effects are more serious than others and if you should experience any of the following events you should discontinue taking fluticasone propionate nasal spray and consult with your doctor as soon as possible.
Psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children)	Potential systemic effects may include a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).	If you get any side effects, talk to your doctor or pharmacist.
Nasal septum perforation	Side effects occurring very rarely: perforation of the nasal septum (the dividing partition in the nose) and ulceration to the nose's mucus membranes - although these usually impact on patients who have had previous surgery to the nose.	Some side effects are more serious than others and if you should experience any of the following events you should discontinue taking fluticasone propionate nasal spray and consult with your doctor as soon as possible.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Use with potent inhibitors of the cytochrome P450 3A4 system	Some medicines can interfere with fluticasone propionate nasal spray. Care should be taken when administering fluticasone propionate in patients taking concurrent drugs that are highly potent inhibitors of the cytochrome P450 3A4 system (e.g. protease inhibitors such as ritonavir).

Missing information

Risk	What is known
Use in pregnant and	There is inadequate evidence of safety in human pregnancy. Administration of

Risk	What is known
breastfeeding women	corticosteroids to pregnant animals can cause abnormalities of foetal development. There may therefore be a very small risk of such effects in the human foetus. The secretion of fluticasone propionate in human breast milk has not been investigated. When fluticasone propionate nasal spray is used in breast feeding mothers the therapeutic benefits must be weighed against the potential hazards to mother and baby.

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 Patient Information Leaflet (PIL). 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

Not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable.