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. The efficacy of fluticasone nasal spray in children aged less than 4 years has not been established.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Ocular events (cataract, glaucoma, intraocular pressure increased, ocular hypertension, chorioretinal disorder)	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. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and	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.

Risk	What is known	Preventability
	topical corticosteroids.	
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.
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).	

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
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.
Adrenal suppression and growth retardation in children and adolescents	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 adrenal suppression, growth retardation in children and adolescents.
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).
Risk of infection	In patients who have tuberculosis, any type of untreated infection, ocular

Risk	What is known (Including reason why it is considered a potential risk)
when used in immunocompromised patients	herpes or have had a recent surgical operation or injury to the nose or mouth, the doctor should weigh possible benefits of the treatment against possible hazards.

Missing information

Risk	What is known
Use in pregnant and breastfeeding women	There is inadequate evidence of safety in human pregnancy. Administration of 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.
Use in patients aged <4 years	The safety and efficacy in children aged less than 4 years has not been established.

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.