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.

Nasal polyps are small growths on the lining of the nose and usually affect both nostrils. The main symptom is a blocked feeling in the nose, which may affect breathing through the nose. Watering from the nose, a feeling of something running down the back of the throat and loss of taste and smell may also occur. In the general population the overall rate of nasal polypos ranges from 1-4%. It is more common in adults, and in men, especially over 50, and rarely affects children and young people except when associated with cystic fibrosis. Approximately 30% of patients with nasal polyps also have environmental allergies.

VI.2.2 Summary of treatment benefits

Drug is used for the treatment of allergic rhinitis and nasal polyps for over a decade.

Patients with intermittent symptoms of allergic rhinitis are often treated adequately with oral antihistamines, decongestants, or both as needed. Regular use of an intranasal corticosteroid spray may be more appropriate for patients with chronic symptoms. Use of nasal corticosteroid may relief ocular symptoms as well.

The only medications effective in shrinking polyps are corticosteroids. Available both orally and topically, they provide a nonspecific anti-inflammatory response that reduces the size of the polyps and improves symptoms related to nasal obstruction

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known (Including reason why it is considered a known risk)	Preventability
Damage of the partition in the nose that separates the nostrils (nasal septum perforation)	This effect can occur in relation to mometasone furoate. Usually, this effect is related to long term use of the corticosteroid nasal sprays. If affected by this adverse effect, stuffy/blocked nose, crusting, episodes of nose-bleeds, smelly discharge from the nose, or a whistling sound during nasal breathing can appear.	Long term use should be avoided. Mometasone furoate nasal spray is not recommended in case of nasal septum perforation
Slowing of growth in children (growth retardation)	Long term use of nasal steroids at high doses may cause slowing of growth in children. Child's height should be checked at intervals during treatment and the dose should be reduced if any effects are seen.	Long term use should be avoided.
Ocular events: clouding of the eye lens (cataract), increase in pressure in the eye (glaucoma), and damages of vascular partition of the eye globe (chorioretinal disorder)	Treatment with corticosteroid nasal sprays like mometasone furoate has led to an increase in pressure in the eye (glaucoma) and/or clouding of the eye lens (cataracts), causing visual disturbances.	Long term use should be avoided.
Psychiatric and behavioural events: state of increased mental and muscular activity (psychomotor hyperactivity), sleeping problems (sleep disorder), nervousness (anxiety), depression, aggression	Drugs from corticosteroids class can cause physical and psychological effects including state of increased mental and muscular activity, sleeping problems, nervousness, depression, and aggression (particularly in children). This often happens if high doses are used for longer periods.	Long term use should be avoided.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Blood sugar level increased (hyperglycaemia)	It is known that drugs from corticosteroids (glucocorticoid) class can cause increased blood sugar levels in patients with and without diabetes, especially at high doses, long term use and systemically used corticosteroids (by mouth or by injections). Though mometasone furoate nasal spray suspension belongs to corticosteroid class of drugs, the risk that its use will cause this effect is very low because the amounts of drug that absorb into body are very small. However, if thirst and increased urination are noticed, especially at the beginning of the treatment, blood sugar levels should be checked.

Adrenal gland function decreased (adrenal suppression)	When starting mometasone furoate nasal spray, the patient may be advised by the doctor to stop other corticosteroid medicines previously used for allergy (either by mouth or injection). This may cause inadequate functioning of adrenal gland and lowering amounts of adrenal hormones being produced. A few people may suffer some undesirable effects, such as joint or muscular pain, weakness and depression. Treatment with higher than recommended doses of mometasone furoate may also cause this effect.
Allergic reactions (hypersensitivity including anaphylactic reaction)	As with any other drug used, allergic reactions such as itchy, watering eyes or patches of red and itchy skin can appear during the use of mometasone furoate. Immediate hypersensitivity (allergic) reactions may occur after use of this product. These reactions may be severe. You should stop taking mometasone furoate nasal spray and get immediate medical help if you experience symptoms such as: swollen face, tongue or pharynx, trouble swallowing, hives, wheezing or trouble breathing
Risk of infection when used in immunocompromised patients	While using Mometasone Furoate Nasal Spray, take special care - if you have or have ever had tuberculosis - if you have any other type of infection - if you are coming into contact with anyone who has measles or chickenpox; contact should be avoided.
Use of mometasone in the presence of existing infections (nose infection, ocular viral infections, tuberculosis or other infections)	Mometasone nasal spray should not be used if there is an existing infection in your nose. You should wait until the infection is resolved before you start using the nasal spray. The doctor should be consulted before taking the medicine if the patient has or have ever had tuberculosis, if he has herpes simplex (virus) infection of the eye or any other type of infection.

Missing information

Risk	**What is known**
Use in children younger than 3 years	The safety and efficacy of Mometasone Furoate Nasal Spray in children under 3 years of age have not been established.
Use during pregnancy or breast-feeding	Pregnant and breast-feeding women should not use mometasone furoate nasal spray unless advised otherwise by their doctor.

VI.2.5 Summary of additional risk minimisation measures by safety concern

Not applicable.

VI.2.6 Planned post authorisation development plan (if applicable)

Not applicable.

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

Version	Date	Safety Concerns	Comment
2.1	06 September 2013	Important identified risks: • Nasal septum perforation • Growth retardation in children receiving prolonged treatment • Ocular events (cataract, glaucoma, intraocular pressure increased, ocular hypertension, chorioretinal disorder) • Psychiatric and behavioural events (psychomotor hyperactivity, sleep disorder, anxiety, depression, aggression) Important potential risks: • Hyperglycaemia (blood glucose increased) • Adrenal suppression • Hypersensitivity (including anaphylactic reaction) • Risk of infection when used in immunocompromised patients • Use of mometasone in the presence of other infections Missing information: • Use in patients aged <6 years • Use in pregnancy and lactation	Approved on 18th September 2013 within DCP procedures: UK/H/4971/01/DC UK/H/5213/01/DC
3.2		Missing information “Use in patients aged <6 years” has been amended to “Use in patients aged <3 years”	Based on the outcome of article 30 of Directive 2001/83/EC, the age limit for mometasone was lowered to 3 years. Further updates were done due to SmPC/PIL changes. Version 3.0 and 3.1 were submitted within the procedure UK/H/6175/001/DC