VI.2. ELEMENTS FOR A PUBLIC SUMMARY

VI.2.1. Overview of disease epidemiology

Rhinitis ("swelling and irritation of the mucous membrane inside the nose") is characterized by nasal symptoms including sneezing, itching and blocked, stuffy or runny nose.

The most common kind of rhinitis is allergic rhinitis that can be caused by things such as:

- Animal fur or house dust mites. This type of allergy can happen at any time of the year and is called "perennial allergic rhinitis" (PAR)

- Pollen. This type of allergy, such as hay fever, can be caused by different pollens in different seasons of the year. This is called "seasonal allergic rhinitis" (SAR)

It is estimated that over 500 million patients suffer from allergic rhinitis which causes major illness and disability worldwide by affecting social life, sleep, school and work with a substantial economic impact.

VI.2.2. Summary of treatment benefits

Triamcinolone acetonide is a corticosteroid ("type of steroid"). The precise mechanism of corticosteroid antiallergic action is unknown, corticosteroids are very effective in the treatment of allergic diseases in man. They have been shown to have a wide range of actions on multiple cell types involved in inflammation (swollen, red, and painful).

Triamcinolone acetonide 55 micrograms/dose as aqueous suspension in nasal spray (TAA-AQ) is a suspension of the corticosteroid, triamcinolone acetonide, in a metered dose nasal spray pump unit (55 micrograms per spray), which has been approved for the treatment of seasonal allergic rhinitis and perennial allergic rhinitis

VI.2.3. Unknowns relating to treatment benefits

TAA-AQ has been on the market for over 15 years and no unknown benefits related to treatment are expected.

VI.2.4. Summary of safety concerns

Table 3 - Important identified risks

Risk	What is known	Preventability
Severe hypersensitivity reaction	Hypersensitivity reactions such as serious allergic reaction which causes swelling of the face, lips, tongue and throat (angioedema) or difficulty in breathing (anaphylaxis), are known reactions observed with triamcinolone acetonide in nasal spray. The frequency of such events is unknown.. No specific groups of patients have been identified with elevated risk of hypersensitivity reaction apart from patients with known hypersensitivity to triamcinolone acetonide or of any of its excipients.	Yes, by avoiding the use of triamcinolone acetonide in nasal spray in patients who are known to be allergic to triamcinolone acetonide or any of the ingredients of triamcinolone acetonide in nasal spray
Reduction in growth velocity in children (how fast they grow)	Growth retardation has been reported in children receiving nasal corticosteroids, including triamcinolone for a long time (over 12 months).	Yes, by regularly checking the eight of the children who have been using triamcinolone acetonide in nasal spray for a long time.
Nasal septum (middle part of the inside of the nose) perforation	Corticosteroids have an inhibitory effect on wound healing, and thus intranasal corticosteroids can increase the risk of	Yes, by limiting the use of triamcinolone acetonide in nasal spray in patients who have

Risk	What is known	Preventability
	nasal septal perforation if used when a patient has an unhealed wound at the nasal septum. The frequency of such event is rare.	recently had a nose operation, or had an injury or ulcer in the nose.

Table 4 - Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Harm for the future baby when given to pregnant women	Limited information is available on the use of triamcinolone acetonide in nasal spray in pregnant women. In animal studies, corticosteroids including triamcinolone acetonide have been shown to induce malformations in foetus (developing baby still inside the mother's body)). Pregnant women may expose their future babies to possible risk.
Decrease of the level of cortisol in the blood in patients previously treated for prolonged periods with oral corticosteroids and/or concomitantly treated with oral corticosteroids	A decrease of the level of cortisol in the blood may occur in patients previously treated for prolonged periods with corticosteroids and/or concomitantly treated with corticosteroids. However,studies on the effects of triamcinolone acetonide in nasal spray have not clearly identified such effect when the medication is used at the recommended dosages.
Ocular disorders	Inhaled and intranasal corticosteroids are associated in the medical literature with a risk of cataract ("Cloudiness of the lens in the eye"). The risk appears greatest at high doses of inhaled and intranasal corticosteroids for prolonged periods). A small risk of glaucoma ("elevated pressure inside the eye ball") with prolonged high doses of inhaled and intranasal corticosteroids has been also reported. The risk of both of these ocular disorders increases with increasing age. It is recommended to monitor patients with a change in vision or previous history of glaucoma and/or cataract. The frequency of such event is unknown.
Infection of the nose and the pharynx with *Candida albicans* (type of yeast)	*Candida albicans* is a type of yeast that is a constituent of the normal gut flora that lives in the human mouth and gastrointestinal tract. Local infection of the nose and the pharynx may develop in patients on long term treatment with corticosteroids. It is recommended to monitor patients for this type of infection.

Table 5 - Important missing information

Risk	What is known
Missing information for lactating women	Triamcinolone acetonide in nasal spray may, like other corticosteroids, pass into human breast milk. Its use is not recommended in lactating women.
Missing information for children aged under 6 years old.	The safety and efficacy of triamcinolone acetonide in nasal spray in children under 6 years of age have not been established and its use in this group of patients is not recommended.

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

"Applicable to Belgium only – additional risk minimization activities:

In the context of the national change of dispensing status from 'medicinal product subject to medical prescription' to 'medicinal product not subject to medical prescription' of Triamcinolone acetonide sanofi-aventis Belgium (UK/H/4484/001/DC) in Belgium, an educational/reminder tool has been developed and will be introduced in Belgium only, in response to a request from Belgian Health Authorities (HA). It is a "pharmacist guide" to be checked by the pharmacist before dispensing the medicinal product without medical prescription to the patients. Its aim is to enhance the appropriate use of the medicinal product available without medical prescription, focusing on the fact that, if it is the first time the patients experienced allergic rhinitis symptoms, the pharmacist should refer them to a physician.

Not applicable in other countries where additional risk minimization measures are not required."

VI.2.6. Planned post authorization development plan

There is no post authorization development plan for triamcinolone.

VI.2.7. Summary of changes to the RMP over time

Table 6 - Summary of changes to the RMP over time

Version	Date	Safety concerns	Comment
1.0	April 2013	Not applicable	First RMP submitted
1.1	August 2013	Infection of the nose and pharynx with *Candida albicans*	Added as important potential risk
		Use in children aged <6 years and not only under 2 years	Added as missing information
1.3*	October 2015	Not applicable	Update to include local annex 11 specific to Belgium in order to meet the Belgian Agency's request in the context of non-prescription status.
1.4	February 2016	Not applicable	Update to include updated Part I/Part VI/Part VII (Annex 11) further to the UK and Belgian Agencies' requests during evaluation of version 1.3
1.5	March 2016	Not Applicable	Update to include updated Part I/Part V/Part VI further to the UK and Belgian's requests during evaluation of version 1.4

*A version 1.2 of this RMP, dedicated to local Belgian update only in the context of national change of dispensing status to 'medicinal product not subject to medical prescription', was submitted to Belgian Health Authorities (HA) and rejected without local evaluation.