8.2 Part VI.2 Elements for a Public Summary

8.2.1 Part VI.2.1 Overview of disease epidemiology

8.2.1.1 Allergic rhinitis (AR)

AR is a very common chronic illness affecting 10% to 40% of children worldwide and the number has significantly increased over the last two decades. Prevalence (number of affected individuals) and seriousness are related to age, with children of school age mostly affected [Nasser M, et al. 2010].

Many countries throughout the world have experienced an increase of AR, which has come to be a major cause of morbidity in developed countries. The pathology underlying AR is a type I

allergy characterized by mucosal inflammation that occurs in response to allergen exposure [Fujieda S, et al. 2012].

Worldwide, more than 400 million individuals have allergic rhinitis, which has a significant impact on the individual's general health. Most patients self-medicate with over-the-counter drugs, but severe cases need treatment with topical corticosteroids and/or immunotherapy [Aasbjerg K, et al. 2012]. AR and asthma represent global health problems for all age groups [Bousquet J, et al. 2012].

8.2.1.2 Urticaria

Drug exposure is one of the main causes of urticaria and represents the second most common cause in acute urticaria. Acute and chronic urticaria is characterized by weals (a red swollen mark) and angioedema (rapid swelling of the area below the skin). The life-time prevalence for urticaria or angioedema is approximately 10-20% [Criado PR, et al. 2006]. Urticaria not only causes a decrease in quality of life, but also affects performance at work and school and, as such, is a member of the group of severe allergic diseases [Zuberbier T, et al. 2009].

8.2.2 VI.2.2 Summary of treatment benefits

Desloratadine is a second-generation antihistamine and is used to improve the symptoms of AR, such as runny nose, sneezing, stuffy nose and nasal itch as well as allergic eye symptoms like red and watery eyes. Additionally, it reduces pruritus and size of hives in patients with urticaria as well.

8.2.3 Part VI.2.3 Unknowns relating to treatment benefits

Large amounts of data on pregnant women (more than 1,000 pregnancy outcomes) indicate no malformative or feto/neonatal toxicity of desloratadine. The effect of desloratadine on newborns/infants as a result of breast-feeding is unknown. Efficacy and safety of desloratadine tablets in children under 12 years of age have not been established. The efficacy of desloratadine tablets has not been clearly demonstrated in trials with adolescent patients 12 through 17 years of age. The safe use of the medicinal product during pregnancy has not been established.

8.2.4 Part VI.2.4 Summary of safety concerns

Table 8-5 Important identified risks

Risk	What is known	Preventability
Allergic reactions including swelling, breathlessness, itching, severe itching of the skin and rash (Hypersensitivity (including anaphylaxis, angioedema, dyspnea, pruritus, rash, and urticaria))	This undesirable effect has been reported very rarely (< 1/10,000) during the post-marketing period. Patients with rare hereditary problem of fructose intolerance, glucose-galactose malabsorption (imperfect absorption of food) or sucrose-isomaltase inadequacy should not take this medicine.	Desloratadine is contraindicated in patients who are allergic to this medication or to any of its ingredients, or to loratadine.

Risk	What is known	Preventability
		During the marketing of desloratadine, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been reported very rarely. If the patient notices any of these serious side effects, he/she should stop taking the medicine and seek urgent medical advice straight away.
Abnormal liver function (including liver inflammation and increased liver enzymes and bilirubin) Abnormal hepatic function (including hepatitis and elevated hepatic enzymes and bilirubin)	Liver inflammation and abnormal liver function tests may occur very rarely (< 1/10,000) with the use of desloratadine.	Patients should inform their doctor if they have medical history or ongoing condition of inflammation of liver.

Table 8-6 Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
A sudden, violent, irregular movement of the body, caused by involuntary contraction of muscles and associated especially with brain disorders (Convulsion)	Convulsions may occur very rarely (< 1/10,000) with desloratadine. It is recommended to administer desloratadine cautiously in patients with prior history or familial history of seizures. The patients should talk to their doctor and may discontinue the treatment if he/she experiences seizure while on treatment. Young children should be monitored as they are more susceptible to develop seizures while on desloratadine therapy.
Unintentional and purposeless movement of the body and the inability to rest or relax (Movement disorder (including psychomotor hyperactivity and restlessness))	Restlessness and increased body movement may occur very rarely (< 1/10,000) with desloratadine. In controlled clinical trials, desloratadine does not have any effect on psychomotor performance.
Abnormally fast heart rhythm due to improper electrical activity in the upper part of the hear (Supraventricular tachyarrhythmia)	Pounding or irregular heartbeat, fast heartbeat may occur very rarely (< 1/10,000) with desloratadine. The frequency of occurrence of slow heartbeat and change in the way the heart beats in children is not known. In multiple dose clinical trial, no statistically or clinically relevant cardiovascular effects were observed.
Heart rhythm condition that can possibly cause fast, disordered heartbeats (QT prolonged)	The frequency of occurrence of QT prolongation is not known. During post-marketing period QT prolonged was a reported undesirable effect in children.

Risk	What is known (Including reason why it is considered a potential risk)
	In clinical trials desloratadine was well tolerated as documented during laboratory teste, ECG interval data including QTc
An experience involving the false perception (the ability to see, hear, or become aware of) of something not present. (Hallucinations)	Hallucinations may occur very rarely (< 1/10,000) with desloratadine.
Unusual behavior in children including state of nervous excitement and feeling of anger and violent behavior Abnormal behavior in pediatric patients (including anger, agitation and aggression)	The frequency of occurrence of abnormal behavior and aggression is not known. The clinical trial related efficacy experience in adolescents (12-17 years) is limited.
Extreme sensitivity to ultraviolet (UV) rays from the sun and other light sources (Photosensitivity)	The frequency of occurrence of photosensitivity with desloratadine is not known.

Table 8-7 Missing information

Risk	What is known
Use in pregnancy	There are no adequate and well-controlled studies in pregnant women; however, the amount of data available indicates no malformative toxicity (feto or neonatal). The use of desloratadine during pregnancy is not recommended.
Use in breast-feeding (Us in lactation)	The effect of desloratadine on newborns/infants is unknown; however it has been identified in breastfed newborns/infants of the treated mothers. Considering the benefit-risk associated to the mother and child the decision must be made whether to discontinue breast-feeding or to discontinue/abstain from desloratadine.
Use in children less than 6 months of age	The effects of desloratadine in poor metabolizers < 2 years of age have not been studied. In children below 6 months of age the most commonly reported adverse reactions include diarrhea, fever and insomnia.

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

All medicines have a summary of product characteristics (SmPC) which provides physicians, pharmacists and other health care professionals (HCPs) with details on how to use the medicine, the risks and recommendations for minimizing them. An abbreviated version of this in lay language is provided in the form of the package leaflet. The measures in these documents are known as routine risk minimization measures.

The SmPC and the Package leaflet (PL) for desloratadine can be found in the desloratadine's EPAR page.

This medicine has no additional risk minimization measures.

8.2.6 Part VI.2.6 Planned post authorization development plan

None

8.2.6.1 Studies which are a condition of the marketing authorization

None

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

N/A (for version 1)