Desloratadine

Version 2.0

Summary of the risk management plan

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Hay fever

Scandinavian studies have demonstrated a cumulative frequency rate of 15% in men and 14% in women. The frequency of hay fever may vary within and among countries. This may be due to geographic differences in the types and potency of different allergens and the overall aeroallergen burden.

While hay fever itself is not life-threatening (unless accompanied by severe conditions that narrow the air ways or severe allergic responses), morbidity from the condition can be significant. Hay fever often coexists with other disorders, such as asthma (condition that narrow the air ways), and may be associated with asthma exacerbations.

Hay fever occurs in persons of all races. Prevalence of hay fever seems to vary among different populations and cultures, which may be due to genetic differences, geographic factors or environmental differences, or other population-based factors.

In childhood, hay fever is more common in boys than in girls, but in adulthood, the occurrence is approximately equal between men and women.

Onset of hay fever is common in childhood, adolescence, and early adult years, with a mean age of onset 8-11 years, but hay fever may occur in persons of any age. In 80% of cases, hay fever develops by age 20 years. The prevalence of hay fever has been reported to be as high as 40% in children, subsequently decreasing with age. In the geriatric population, running nose is less commonly allergic in nature[i]

References:

Itchy skin rash

Acute itchy skin rash affects 15-20% of the general population at some time during their lifetime. Acute itchy skin rash is usually self-limited and commonly resolves within 24 hours but may last up to 6 weeks. Chronic itchy skin rash lasts more than 6 weeks. Neither acute nor chronic itchy skin rash results in long-term consequences other than generalized fear and mental state characterized by extreme sadness. The mental state characterized by extreme sadness can be severe enough to lead to suicide in rare cases. Also, many of the diseases associated with chronic itchy skin rash may cause very significant morbidity and mortality.

Incidence rates for acute itchy skin rash are similar for men and women; chronic itchy skin rash occurs more frequently in women (60%).

Itchy skin rash can occur in any age group, although chronic itchy skin rash is more common in the fourth and fifth decades.[ii]

VI.2.2 Summary of treatment benefits

In a programme surveillance studies comprising 77 880 patients, aged 12 years of age or

above, all patients receiving oral desloratadine 5 mg once daily for a mean duration of up to 40.4 days, tolerability was rated as excellent/good by 99.1% of investigators and 98.5% of subjects. Desloratadine therapy significantly reduced nasal and ocular symptom severity, itching and wheals, and sleep and activity disruption, as indicated by a reduction in mean total and individual symptom scores, and reported impairment of sleep and daily activities. The efficacy of desloratadine was rated as significantly greater by 59.4-88.0% of subjects who had previously received one drug therapy with cetirizine, fexofenadine, loratadine or mizolastine. The percentage of subjects who rated onset of symptom relief with desloratadine as faster than previous treatment ranged from 51.6% to 82.4%. Desloratadine was safe, well tolerated and efficacious in these studies. An analysis of subjects who had received previous monotherapy with a second- generation antihistamine found that most subjects rated efficacy as higher than their previous treatment, with a faster onset of symptom relief.

A total of 9246 patients with chronic itchy skin rash participated (63% female) in a study. Itching, number of swellings and the size of the largest swelling decreased significantly desloratadine therapy. In patients that received previous therapy with cetirizine, loratadine or fexofenadine alone, patients rated the onset of efficacy of desloratadine as faster in 55.5%, 54.7% and 57.6% of cases, respectively. The occurrence of adverse events was low (0.5% of patients) and no serious adverse events were reported.[iii]

VI.2.3 Unknowns relating to treatment benefits

As stated in the SPC, there is limited clinical trial efficacy experience with the use of desloratadine in adolescents 12 through 17 years of age. Section VI.2.2 of this RMP presented a large study in which this subpopulation has been included and concluded both efficacy and tolerance of desloratadine. Also, the SmPC states that there are no or limited amount of data from the use of desloratadine in pregnant or lactating women.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
NA	NA	NA

Important potential risks

Risk	What is known
Sleepiness (somnolence)	In clinical trials there was no excess in the frequency of oc-

Risk	What is known
	currence of somnolence as compared to placebo (substance with no medicinal effect).
Fits (seizures)	Fits were reported in post marketing experience for desloratadine.
Blood tests which show changes in the way the liver is working (liver enzyme elevations)	Blood tests which show changes in the way the liver is working have been observed in post marketing experience for desloratadine.
Inflammation of the liver causing yellowing of the skin or eyes (hepatitis)	Inflammations of the liver causing yellowing of the skin or eyes have been observed in post marketing experience for desloratadine.
Faster heart beat (tachycardia)	Faster heart beats have been observed in post marketing experience for desloratadine
Serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis)	Serious allergic reactions which cause difficulty in breathing or dizziness have been observed in post marketing experience for desloratadine.
Serious allergic reaction which causes swelling of the face or throat (angioedema)	Serious allergic reactions which causes swelling of the face or throat have been observed in post marketing experience for desloratadine

Missing information

Risk	What is known
Use in children under 12 years	Desloratadine is not recommended in children under 12 years old. Efficacy and safety of desloratadine tablets in children under 12 years of age have not been established.
Use during pregnancy and breast-feeding	In animal studies, desloratadine has not caused birth defects. The safe use of the medicinal product during pregnancy and breast feeding has not been established. The use of desloratadine during pregnancy and breast feeding is therefore not recommended.

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 package leaflet (PL). 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

No post-authorisation safety or efficacy studies are ongoing or are planned to be conducted for desloratadine.

VI.2.7 Summary of changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
1.0	25/02/2014	Missing information: - Use in children under 12 years - Use in pregnancy	Initial version- not approved
2.0		Addition of the following potential risks:	

Version	Date	Safety Concerns	Comment
		- Somnolence - Seizures - Liver enzyme elevations - Hepatitis - Tachycardia - Anaphylaxis - Angioedema Rephrasing of missing information ``use in pregnancy`` to ``use during pregnancy and lactation``	