PUBLIC SUMMARY OF RISK MANAGEMENT PLAN

FEXORIN 120 MG FILM-COATED TABLETS

ORION CORPORATION

DATE: 21-08-2014, VERSION 02

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Seasonal allergic rhinitis (Hay fever)

Seasonal allergic rhinitis (hay fever) is an inflammatory condition of the upper airways that occurs in response to exposure to allergy causing agents (allergens) such as tree, grass, and weed pollens. Seasonal allergic rhinitis is most often caused by pollen carried in the air during different times of the year in different parts of the country. Seasonal allergic rhinitis shows signs including nasal discharge, itchy nose, sneezing, and/or stuffy nose.

One in six people is affected by seasonal allergic rhinitis. Seasonal allergic rhinitis has peak prevalence in adolescence and early adulthood, and there is no difference between the sexes in prevalence.

Chronic idiopathic urticaria

Urticaria is commonly referred to as hives, is a kind of skin rash notable for pale red, raised, itchy bumps. Hives might also cause a burning or stinging sensation. When hives last longer than six weeks and the cause of hives is unknown it is called as chronic idiopathic urticaria. They can be painful and cause wheels. Chronic idiopathic urticaria could also be result of inappropriate response of the body against substances and tissues normally present in the body (autoimmunity).

Chronic idiopathic urticaria (CIU) is a common skin condition that affects 0.1-3 % of people in the USA and Europe and accounts for nearly 75 % of all chronic urticaria cases.

VI.2.2 Summary of treatment benefits

Not applicable.

VI.2.3 Unknowns relating to treatment benefits

- There are no adequate data from the use of fexofenadine hydrochloride in pregnant women. There are no data on the content of human milk after administering fexofenadine hydrochloride.
- There is no adequate data on use of fexofenadine in elderly and patients with impaired renal or hepatic function.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Heart related disorders (Cardiovascular events like increased heart beat (tachycardia) and palpitations)	Heart disorders such as abnormally fast heart rate (tachycardia) and sensation of beating of heart (palpitations) have been reported in clinical trials.	Yes. Risk of heart related disorders has been mentioned in Section 2 (What you need to know before you take Fexorin) and section 4 (Possible side effects) of PIL. As per Section 2 (What you need to know before you take Fexorin) of PIL, the patients should inform their physicians if they have history of heart related conditions.
Allergic reactions (hypersensitivity) including anaphylactic reactions	Allergic reactions (hypersensitivity) with manifestations such as giant hives (angioedema), chest tightness, difficulty in breathing (dyspnoea), flushing and whole body allergic reaction (systemic anaphylaxis) have been reported in clinical trials.	Yes. Risk of allergic reactions has been mentioned in Section 2 (What you need to know before you take Fexorin) and section 4 (Possible side effects) of PIL. As per section 2 (What you need to know before you take Fexorin), fexofenadine is contraindicated in patients with known allergy to fexofenadine.
Co-administration with erythromycin or ketoconazole	Co-administration of fexofenadine hydrochloride with erythromycin or ketoconazole has been found to result in a 2-3 times increase in the level of fexofenadine in blood (plasma). The changes were not accompanied by any effects on the QT interval of electrocardiogram and were not associated with any increase in adverse reactions compared to the medicinal products given singly.	Yes. The patients and physicians should be informed to avoid the co-administration of fexofenadine hydrochloride with erythromycin or ketoconazole.

Important potential risks

Risk	What is known
None	

Missing information

Risk	What is known
Use in elderly and patients with kidney or liver problems (renally or hepatically impaired patients)	As with most new medicinal products there is only limited data with respect to use of fexofenadine in the older patients and patients with kidney or liver problems (renally or hepatically impaired patients). Fexofenadine hydrochloride should be administered with care in these special groups. Studies in special risk groups (older people, kidney or liver impaired patients) indicate that it is not necessary to adjust the dose of fexofenadine hydrochloride in these patients.
Pregnant and breast feeding women	There are no adequate data from the use of fexofenadine hydrochloride in pregnant women. Limited animal studies do not indicate direct or indirect harmful effects with respect to effects on pregnancy, embryonal/foetal development, parturition or postnatal development. Fexofenadine hydrochloride should not be used during pregnancy unless clearly necessary. There are no data on the content of human milk after administering fexofenadine hydrochloride. However, when terfenadine was administered to nursing mothers fexofenadine was found to cross into human breast milk. Therefore fexofenadine hydrochloride is not recommended for mothers breast-feeding their babies.

VI.2.5 Summary of risk minimisation measures by safety concern

Not applicable.

VI.2.6 Planned post authorisation development plan

Not applicable.