Levocetirizin Stada

24.1.2014, Version V1.1

PUBLIC SUMMARY OF RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

Levocetirizin STADA 5 mg, film-coated tablets

VI.2.1 Overview of disease epidemiology

Allergic rhinitis is an allergic inflammation of the nasal airways that occurs when allergens (e.g. pollen, dust) are inhaled by an individual with a sensitized immune system. The allergen triggers the production of the immunoglobulin IgE that finally causes the release of inflammatory mediators such as histamine. This usually causes sneezing, itchy and watery eyes, swelling and inflammation of the nasal passages, and an increase in mucus production. Rhinitis (and sinusitis) are among the most common medical conditions and are frequently associated. In Western societies, an estimated 10% to 25% of the population have allergic rhinitis, with 30 to 60 million persons being affected annually in the United States. Treatment options include avoiding the allergen, other antihistamines, glucocorticoids given as nasal spray or systemically in severe cases.
Nettle rash (urticatia) is a kind of skin rash characterized by pale red, raised, itchy wheals that can appear anywhere on the surface of the skin. It is frequently caused by allergic reactions; however, there are many nonallergic causes. The reaction is caused by a release of inflammatory mediators, including histamine from cutaneous mast cells that leads to fluid leakage from blood vessels. Acute urticaria lasts less than 6 weeks. Urticaria lasting more than 6 weeks is defined as chronic urticaria, and an etiology is seldom identified. Chronic urticaria may have an autoimmune basis. Urticaria may affect up to 20% of the population at some time in their lives. In half of the patients, psychosocial factors are likely to contribute to the development of chronic urticaria. Treatment options include awareness of individual triggers, other antihistamines or systemic corticoids in severe cases.

VI.2.2 Summary of treatment benefits

Levocetirizine dihydrochloride is the active ingredient of Levocetirizine dihydrochloride 5 mg. Levocetirizine dihydrochloride 5 mg is an antiallergic medication.

For the treatment of signs of illness (symptoms) associated with:
- allergic rhinitis (including persistant allergic rhinitis);
- nettle rash (urticaria).

VI.2.3 Unknowns relating to treatment benefits

Levocetirizine dihydrochloride has not been established in children under 6 years of age.

The safety of Levocetirizine dihydrochloride during pregnancy has not been studied and the potential risk is unknown.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Hypersensitivity reaction to Levocetirizine dihydrochloride or an antihistamine (Hypersensitivity to levocetirizine or to other piperazine derivatives)	The frequency of allergic reactions (that might include swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties, hives, sudden fall in blood pressure leading to collapse or shock) is unknown.	Levocetirizine dihydrochloride should be discontinued promptly and appropriate treatment should be initiated in case of an allergic reaction. Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Impairment of kidney function (Renal impairment)	The excretion of Levocetirizine dihydrochloride depends on the kidney function. Is is recommended to adjust the dosing intervals in patients with impaired kidney function.	Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease. Usage in patients with severe impairment of kidney function (severe renal failure with a creatinine clearance below 10 ml/min) is forbidden. Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Iridocyclitis	Single cases of iridocyclitis have been reported from post-marketing experience in temporal association with the intake of levocetirizin. However, a causal relationship has not been established.
Effects on the central nervous system when concomitantly administered with alcohol	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
Urinary retention	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.

Missing information

Risk	What is known
Pregnant women	For the medicinal product no clinical data on usage during pregnancy are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, childbirth of further development. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) 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 studies have been imposed or are planned.

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

Not applicable