
PUBLIC SUMMARY OF RISK MANAGEMENT PLAN (RMP)

LEVOCETIRIZIN ORION FILM-COATED TABLETS

ORION OYJ

DATE: 29-04-2015, VERSION 1

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Allergies are quite common. Both genes and environment play a role in allergy.

The immune system normally protects the body against harmful substances, such as bacteria and viruses. It also reacts to foreign substances called allergens, which are generally harmless and in most people do not cause a problem. However in a person with allergies, the immune response is oversensitive. When it recognizes an allergen, the immune system launches a response. Chemicals such as histamines are released. These chemicals cause allergy symptoms.

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. This usually causes sneezing, itchy and watery eyes, swelling and inflammation of the nasal passages, and an increase in mucus production. In Western societies, an estimated 10% to 25% of the population have allergic rhinitis. Treatment options include avoiding the allergen, other antihistamines, glucocorticoids given as nasal spray or systemically in severe cases.

Nettle rash (urticaria) 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 as well. 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

This medicinal product contains levocetirizine as active ingredient. It is an antiallergic drug and belongs to a group of medicines called antihistamines. It works by blocking the action of histamine, a substance in the body that causes allergic symptoms.

Levocetirizine can be used for the treatment of signs of illness (symptoms) associated with:

- allergic rhinitis (including persistent allergic rhinitis)
- nettle rash (urticaria).

VI.2.3 *Unknowns relating to treatment benefits*

Safety and efficacy of this tablet formulation is not established in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation. It is recommended to use another formulation of levocetirizine appropriate for children under 6 years of age.

VI.2.4 *Summary of safety concerns*

Important identified risks

Risk	What is known	Preventability
Impairment of kidney function	Elimination of levocetirizine from the body is mainly done via excretion through kidneys. If kidneys are not functioning properly, elimination may be delayed and the amount of medicine in the body may increase above normal level.	Patients with impaired kidney function may be given a lower dose or dosing interval can be adjusted according to the severity of their kidney disease. Patients with severe impairment of kidney function (severe renal failure with a creatinine clearance below 10 ml/min) cannot use levocetirizine.
Difficulty/inability to empty the bladder (Urinary retention)	Levocetirizine may increase the risk for difficulty/inability to empty the bladder.	Caution should be taken in patients with predisposing factors for this adverse effect e.g. patients with spinal cord disorders or enlarged prostate.
Administration in patients with epilepsy or risk for convulsions/seizures	Based on post-marketing experience convulsions are listed as adverse drug reactions. Frequency is not known.	Caution is recommended in epileptic patients and patients who are at risk of convulsions.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Effects on the central nervous system when concomitantly administered with alcohol	Caution is recommended with intake of alcohol. In sensitive patients simultaneous administration of cetirizine or levocetirizine may have effects on the central nervous system, although it has been shown that cetirizine does not potentiate the effect of alcohol.

Missing information

Risk	What is known
Administration during pregnancy	Caution should be administered in pregnant women. For levocetirizine no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects.

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. The Summary of Product Characteristics and the Package leaflet for this medicinal product can be found in the national authority's web page.

This medicine has no additional risk minimisation measures.

VI.2.6 *Planned post authorisation development plan (if applicable)*

Not applicable.

VI.2.7 *Summary of changes to the risk management plan over time*

Not applicable.