VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

The association of allergic nasal and ocular symptoms (rhinoconjunctivitis) is common. Most children with allergic conjunctivitis have allergic rhinitis. Older population studies estimate a prevalence of 15-20% of allergic conjunctivitis, but more recent studies implicate rates as high as 40%. Ocular symptoms are common and contribute to the burden of allergic rhinitis and lower quality of life. Ocular allergies rank a very close second and at times may overcome the primary complaints of nasal congestion in rhinoconjunctivitis patients (1). Patients report bilateral mild to intense ocular itching, conjunctival hyperemia, photosensitivity (photophobia in severe cases), eyelid edema, and watery or stringy discharge. In more severe forms, larger tarsal conjunctival papillae, conjunctival scarring, corneal neovascularization, and corneal scarring with variable loss of visual acuity can occur. Main treatment options are symptomatic measures, topical antihistamines, NSAIDs, mast cell stabilizers, or a combination. Topical corticosteroids or cyclosporine can be used for recalcitrant cases (2).

VI.2.2 Summary of treatment benefits

Olopatadine is a medicine used for the treatment of signs and symptoms of seasonal allergic conjunctivitis. It works by reducing the intensity of the allergic reaction. Olopatadine is a potent selective antiallergic/antihistaminic agent that exerts its effects through multiple distinct mechanisms of action. It antagonises histamine (the primary mediator of allergic response in humans) and prevents histamine induced inflammatory cytokine production by human conjunctival epithelial cells. Data from in vitro studies suggest that it may act on human conjunctival mast cells to inhibit the release of pro-inflammatory mediators. In patients with patent

nasolacrimal ducts, topical ocular administration of olopatadine was suggested to reduce the nasal signs and symptoms that frequently accompany seasonal allergic conjunctivitis. It does not produce a clinically significant change in pupil diameter.

These studies were conducted for OPATANOL by Alcon Laboratories (U.K) Limited and not by Mylan.

VI.2.3 Unknowns relating to treatment benefits

Not applicable

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Allergy (Hypersensitivity to the active ingredient or excipients)	If you are allergic to olopatadine or any of the other ingredients of this medicine *do not take olopatadine Mylan*	Yes, by monitoring for early symptoms. Tell your doctor immediately, if you notice any symptoms of an allergic reactions.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Corneal disorders (Keratopathy (for the excipient benzalkonium chloride))	Olopatadine Mylan conatins benzalkonium chloride which may cause disolouration to contact lenses and eye irritation. Patients should avoid contact with soft contact lenses and remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

Missing information

Risk	**What is known (Including reason why it is considered a potential risk)**
Use in pregnant or breast feeding women	Olopatadine is not recommended for use during pregnancy. Do not use this medicine if you are breast-feeding as olopatadine may get into your breast milk.
Use in children under 3 years of age	Olopatadine should not be used in children under the age of 3 years.

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. 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 studies planned.

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

Not applicable.