

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Allergic conjunctivitis (AC) is an inflammation of the lining of the eye (conjunctiva), caused by a reaction of the body's immune system. It can be caused by an infection or an allergic reaction.

It is estimated that AC is suffered by 18-20% of the population (Bielory, 2007) and the incidence is increasing. A recent report stated that up to 40% of people have suffered from AC at one time in their lives (Nye et al., 2013).

There are different types of AC. About 95% of those who suffer from AC will have one of the two commonest forms of the diseases, either (i) "Seasonal Allergic Conjunctivitis" called hayfever, which usually occurs in the spring, when the grass pollen count is high, or (ii) "Perennial Allergic Conjunctivitis", which is an allergic reaction to allergens such as animal dander or house dust mite (Nye et al., 2013). These are not serious, but patients will suffer from itchy, weepy, red and swollen eyes, which can be uncomfortable and can affect sleep and work (Mishra et al., 2011). However, they will not usually cause any long-term damage to the eyes.

There are also some rarer, more serious forms of AC. These are (i) Vernal Keratoconjunctivitis, which occurs most often in boys and young men living in warm climates (ii) Atopic Keratoconjunctivitis, found in patients who also suffer from eczema and (iii) Giant Papillary Conjunctivitis, which is an allergic reaction to contact lenses or contact lens solution. These more serious forms of AC cause long-term inflammation of the eye which can lead to ulcers and scarring and may eventually affect patients' eyesight

All patients who suffer from AC are more likely to have a history of allergy and may also suffer from diseases such as asthma and rhinitis.

VI.2.2 Summary of treatment benefits

Lecrolyn sine eye drops contains the medicine sodium cromoglicate. This has been used since the 1970s for the treatment of allergic conjunctivitis.

Sodium cromoglicate works by preventing the reaction that causes the eyes to become inflamed and uncomfortable. It doesn't stop the reaction once it has started. So it usually takes a few days before the effect of sodium cromoglicate becomes noticeable and during this time, other medicines, such as anti-histamines, will also need to be used, to treat the symptoms of AC. To stop the reaction happening again, the sodium cromoglicate eye drops need to keep being instilled into the eyes after the reaction is over. Lecrolyn sine eye drops, does not contain any preservative, so can be used together with contact lenses.

VI.2.3 Unknowns relating to treatment benefits

Lecrolyn sine is available for the treatment of adults and children; eye drops containing sodium cromoglicate are a well-established treatment for AC in this group of patients. There is more limited experience in the treatment of pregnant and breast-feeding women, but results of animal tests have not shown that it causes any harmful effects to the baby. Furthermore, Lecrolyn sine eye drops are applied directly to the eyes and only a very small amount of sodium cromoglicate is absorbed into the body. Lecrolyn sine eye drops can, therefore, be used by pregnant and nursing mothers.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
None		

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Hypersensitivity (allergy)	<p>There have been only occasional reports of allergic reactions to sodium cromoglicate eye drops.</p> <p>Lecrolyn sine eye drops contains the active ingredient, sodium cromoglicate, which has been widely used for many years in eye drop formulations and other medicines and only a very small number of people have reported allergic reactions to it. The other ingredients in the eye drops have likewise been widely used for many years in different medicines and foodstuffs.</p> <p>However, it is still possible that patients will be allergic to Lecrolyn sine eye drops.</p>
Use of Lecrolyn sine eye drops for a different eye disease to allergic conjunctivitis.	<p>Lecrolyn sine can be obtained without a prescription. It is authorised for the treatment of adults and children with allergic conjunctivitis.</p> <p>However, as it can be obtained without a prescription, there is a possibility that patients with a different eye disease may treat themselves with Lecrolyn sine.</p>

Important missing information

Risk	What is known
Use in pregnant or breast-feeding women	<p>No effects during pregnancy or breast-feeding are expected, since the amount of sodium cromoglicate absorbed into the body after instillation of Lecrolyn sine eye drops will be insignificant.</p> <p>Sodium cromoglicate, the active ingredient of Lecrolyn sine eye drops, has been used in eye drops and other medicines for many years without any reports of adverse effects in pregnant or breast-feeding women.</p>

VI.2.5 Summary of additional risk minimisation measures by safety concern

Not applicable.

VI.2.6 Planned post authorisation development plan

Not applicable.

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

Not applicable.