LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lecrolyn sine
(sodium cromoglicate)

SE/H/1402/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelverket.se E-mail: registrator@mpa.se

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Lecrolyn sine

(sodium cromoglicate)

Eye drops, solution, 40 mg/ml

This is a summary of the public assessment report (PAR) for Lecrolyn sine. It explains how Lecrolyn sine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Lecrolyn sine.

For practical information about using Lecrolyn sine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lecrolyn sine and what is it used for?
Lecrolyn sine is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance. The reference medicine for Lecrolyn sine is Lomudal.

Lecrolyn sine contains the active substance called sodium cromoglicate. This belongs to a group of medicines called anti-allergics. Lecrolyn sine is used to treat eye symptoms due to allergy.

How does Lecrolyn sine work?
Lecrolyn sine works by stopping the release of the natural substances like histamine in your eyes that can lead to an allergic reaction. Signs of an allergic reaction include itchy, watery, red or inflamed eyes and puffy eyelids. Usually both eyes are affected.
These symptoms occur usually in spring or summer when pollen from grasses or trees comes into contact with the eyes of people who are sensitive to them.

How is Lecrolyn sine used?
The pharmaceutical form of Lecrolyn sine is solution for eye drops.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Lecrolyn sine have been shown in studies?
Because Lecrolyn sine is a hybrid application and is considered to be therapeutically equivalent, to the reference product Lomudal, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Lecrolyn sine?
For the full list of all side effects reported with Lecrolyn sine, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Lecrolyn sine approved?
This medicine is similar to a reference medicine containing the same active substance.
No new or unexpected safety concerns arose from the application. Therefore, the Medical

Products Agency in Sweden decided that Lecrolyn sine's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Lecrolyn sine?
A risk management plan has been developed to ensure that Lecrolyn sine is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lecrolyn sine, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Lecrolyn sine
The marketing authorisation for Lecrolyn sine was granted on 2015-11-19 in Sweden.

The full PAR for Lecrolyn sine can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Lecrolyn sine, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2015-12.