SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Lecrolyn sine 40 mg/ml eye drops, solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 40 mg sodium cromoglicate.
For the full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.
Clear, colourless or slightly yellowish solution with a pH of 4.0-6.0 and an osmolality of 260-340 mOsm/kg.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Allergic conjunctivitis in adults and children.

4.2 Posology and method of administration

Posology
The dose should be determined individually for each patient.

Normal dose for children and adults:
1 to 2 drops into each eye two times per day.

Lecrolyn sine should be used regularly to obtain an optimal control of the symptoms.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
Data on a limited number of exposed pregnancies indicate no adverse effects of cromoglicate on pregnancy or the fetus / newborn child. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal / fetal development, parturition or postnatal development. Since systemic exposure of cromoglicate is negligible after topical application to the eye, no effects on the fetus / nursing infants are expected. Lecrolyn sine can be used during pregnancy.
Breastfeeding
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to sodium cromoglicate is negligible. Lecrolyn sine can be used during breastfeeding.

Fertility
No effects on fertility are anticipated since systemic exposure to sodium cromoglicate is negligible. Sodium cromoglicate has not affected fertility in animals, even in high systemic doses.

4.7 Effects on ability to drive and use machines
As with other eye drops, instillation of Lecrolyn sine can cause local irritation and blurred vision that may transiently affect the ability to drive and use machines.

4.8 Undesirable effects
Undesirable effects are listed below as MedDRA preferred term by system organ class and absolute frequency.
Frequencies are defined as:
Common (≥ 1/100 to < 1/10).
Not known (cannot be estimated from the available data)

Immune system disorders
Not known: Hypersensitivity reactions

Eye disorders
Common: Transient stinging or local irritation

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system (will be completed according to Appendix V).

4.9 Overdose
No information is available about adverse reactions related to overdosing.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacoterapeutic group: Decongestants and Antiallergics.
ATC code: S01GX01.

Mechanism of Action
Lecrolyn sine is a preparation for the treatment of allergic conjunctivitis. The mechanism of action is not completely understood, but animal studies and in vitro studies have shown that the active ingredient sodium cromoglicate prevented the degranulation of the mast cells, and thereby the release of histamine and other inflammation-causing substances.

5.2 Pharmacokinetic properties
Sodium cromoglicate penetrates poorly the cornea. The absorption of sodium cromoglicate from the eye's mucous membranes into the systemic circulation is negligible and it is excreted unchanged in bile and in urine.

5.3 Preclinical safety data

There are no preclinical data of relevance that are not addressed in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Disodium edetate
Polyvinylalcohol
Water for injection.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.
Opened container: 8 weeks.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

6.5 Nature and contents of container

White LDPE bottle fitted with a white dropper applicator of HDPE and silicone, with a blue tip and a white HDPE cap, containing 5 ml or 10 ml solution.

Packages of 1, 2 or 3 bottle(s) (5 mL) and package of 1 bottle (10 ml).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Santen Oy
Niittyhaankatu 20
33720 Tampere
Finland
8 MARKETING AUTHORISATION NUMBER

<To be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

2016-11-14