SCHEDULING STATUS

S1

1 NAME OF THE MEDICINE

LECROLYN 20 mg/mL eye drops, solution

LECROLYN 40 mg/mL eye drops, solution

LECROLYN 20 mg/mL SDU eye drops, solution

LECROLYN 40 mg/mL SDU eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

LECROLYN 20 mg/mL eye drops contains 20 mg sodium cromoglicate per 1,0 mL.

LECROLYN 40 mg/mL eye drops contains 40 mg sodium cromoglicate per 1,0 mL

LECROLYN 20 mg/mL SDU contains 20 mg sodium cromoglicate per 1,0 mL.

LECROLYN 40 mg/mL SDU contains 40 mg sodium cromoglicate per 1,0 mL.

Excipient with known effect:

LECROLYN 20 mg/mL contains a preservative (benzalkonium chloride 0,004 % *w/v*)

LECROLYN 40 mg/mL contains a preservative (benzalkonium chloride 0,008 % *w/v*)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Colourless or slightly yellowish clear solution.

The pH of the eye drop solution is:

LECROLYN 20 mg/mL: 4,5 – 5,5

LECROLYN 40 mg/mL: 4,5 – 5,5

LECROLYN 20 mg/mL SDU: 5,0 – 7,0

LECROLYN 40 mg/mL SDU: 4,5 – 6,5

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Allergic conjunctivitis.

4.2 Posology and method of administration

Posology

LECROLYN 20 mg/mL and LECROLYN 20 mg/mL SDU eye drops

Adults and children over 4 years: Instil 1 – 2 drops into each eye four times a day. The dose in the pipette is sufficient for both eyes. A single dose unit is intended for use on one occasion only. Opened pipettes must be discarded after use. Since therapy with sodium cromoglicate is essentially prophylactic, it is important that patients who benefit are instructed to maintain regular dosage.

For children under 4 years: Consult your doctor.

LECROLYN 40 mg/mL and LECROLYN 40 mg/mL SDU eye drops

Adults and children over 4 years: Instil 1 – 2 drops into each eye four times a day. The dose in one pipette is sufficient for both eyes. A single dose unit is intended for use on one occasion only. Opened pipettes must be discarded after use. Since therapy with sodium cromoglicate is essentially prophylactic, it is important that patients who benefit are instructed to maintain regular dosage.

Method of administration

For ocular use only.

4.3 Contraindications

Hypersensitivity to sodium cromoglycate, benzalkonium chloride or to any of the excipients LECROLYN listed in section 6.1.

4.4 Special warnings and precautions for use

LECROLYN eye drops (multidose) contain benzalkonium chloride as a preservative and therefore cannot be used with soft contact lenses.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. The possibility of adverse effect on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological operations cannot be excluded, regular ophthalmological examination is required.

Benzalkonium chloride should be used with caution in patients with dry eyes, patients where the cornea may be compromised or in patients over an extended period with extensive ocular disease.

Patients should be monitored in case of prolonged use.

LECROLYN can be used prophylactically. Patients should seek advice before they discontinue use of LECROLYN.

For LECROLYN multidose units, the solution should be discarded 1 month after first opening the bottle or if any turbidity develops. Do not use if the bottle has been opened prior to receipt.

Where concomitant steroid and LECROLYN treatment has rendered it possible to reduce the steroid dose, precautions must be taken to prevent a severe attack if/when LECROLYN is withdrawn from the treatment regime.

LECROLYN SDU (single dose units) eye drops do not contain preservatives. LECROLYN SDU eye drops should be used immediately after opening the pipettes and any remaining contents discarded after use (see section 4.2).

LECROLYN should be administered in the conjunctival sac of the affected eye. To avoid contamination, the tip of the container/pipette should not touch the eye or any surface (see section 4.4).

As with most ophthalmic preparations, contact lenses should be removed before each application and may be inserted after 15 minutes.

In case of concomitant treatment with other eye drops, instillations should be 15 minutes apart.

LECROLYN 20 mg/mL eye drops contains benzalkonium chloride

LECROLYN contains 0,00014 mg benzalkonium chloride in each drop (0,0035 mL) which is equivalent to 0,04 mg/mL.

LECROLYN 40 mg/mL eye drops contains benzalkonium chloride

LECROLYN contains 0,00024 mg benzalkonium chloride in each drop (0,0030 mL) which is equivalent to 0,08 mg/mL.

Paediatric population

From the limited data available, there is no difference in the adverse event profile in children compared to adults. Generally, however, eyes in children show a stronger reaction for a given stimulus than the adult eye. Irritation may have an effect on treatment adherence in children.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Transient stinging or blurred vision may occur on instillation (see section 4.8). Do not drive or operate machinery until proper vision is restored.

4.8 Undesirable effects

List of adverse reactions

Immune system disorders:

Frequency unknown: Hypersensitivity reactions (including headache, skin rash, bronchospasm, breathlessness, anaphylaxis).

Eye disorders:

Less frequent: Local irritation.

Frequency unknown: Transient burning or stinging and blurring may occur after instillation.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of LECROLYN is important. It allows continued monitoring of the benefit/risk balance of LECROLYN. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

As sodium cromoglicate is absorbed only to a very limited extent from eye drops, no action other than medical observation should be necessary. In the event of accidental ingestion, symptomatic treatment is recommended.

If a hypersensitive reaction occurs, withdraw treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 15.4 Ophthalmic preparations (Others)

Pharmacotherapeutic group: Ophthalmologicals; other antiallergics

ATC code: SO1GX01

An anti-allergic medicine that acts mainly by inhibiting release of inflammatory mediators.

Sodium cromoglicate has no intrinsic vasoconstrictor or antihistamine activity.

5.2 Pharmacokinetic properties

Due to lipid insolubility, sodium cromoglicate is poorly absorbed following administration to the eye.

Trace amounts (less than 0,01 %) of the sodium cromoglicate does penetrate into the aqueous humour and clearance from this chamber is virtually complete within 24 hours after treatment is stopped.

Sodium cromoglicate is not metabolised.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

LECROLYN eye drops

Benzalkonium chloride, Boric acid, Disodium edetate, Water for injection.

LECROLYN SDU eye drops

Sodium chloride, Water for injection.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened

24 months.

After first opening

LECROLYN eye drops: The eye drops must be used within one month after opening the bottle.

LECROLYN SDU eye drops: The single dose units (pipettes) in an opened pack (foil sachet) should be used within one month after opening the hermetic foil. Upon opening a single dose unit, the unit must be used immediately and discarded with any remaining solution.

6.4 Special precautions for storage

LECROLYN eye drops and LECROLYN SDU eye drops

Store at or below 25 ºC, do not freeze.

Protect from light.

6.5 Nature and contents of container

LECROLYN eye drops

The multi dose container is a 10 mL transparent, soft low density polyethylene (LDPE) eye drop bottle with a pigmented (white) hard high density polyethylene (HDPE) cap.

Pack size: 1 multi dose container.

LECROLYN SDU eye drops

The unit dose container is low density polyethylene (LDPE) resin pipettes packed into a carton.

Pack sizes: Unit dose containers in strips of ten are packed into hermetic foil.

LECROLYN 20 mg/mL: 40 pipettes of 0,25 mL, 100 pipettes of 0,25 mL. 4 or 10 blister strips in foils are packed into a carton.

LECROLYN 40 mg/mL: 60 pipettes of 0,25 mL. 6 blister strips in foils are packed into a carton.

6.6 Special precautions for disposal and other handling

Not applicable.

7 HOLDER OF CERTIFICATE OF REGISTRATION

iPharma (Pty) Ltd

124 Elevation Avenue, Randjesfontein

Midrand, 1683, South Africa

8 REGISTRATION NUMBER

LECROLYN 20 mg/mL eye drops: 31/15.4/0322

LECROLYN 40 mg/mL eye drops: 31/15.4/0323

LECROLYN 20 mg/mL SDU eye drops: 31/15.4/0320

LECROLYN 40 mg/mL SDU eye drops: 31/15.4/0321

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14 February 2001

10 DATE OF REVISION OF THE TEXT

12 June 2023