SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE MEDICINAL PRODUCT

ALLERCROM Eye Drops (Cromolyn Sodium Ophthalmic Solution USP 2% w/v)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cromolyn Sodium .....2.0 % w/v
Benzalkonium Chloride .....0.01 % w/v
(As preservative)
Water for Injection ..... q.s.

3. PHARMACEUTICAL FORM

Ophthalmic Solution

Description
Almost Colorless, clear solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ALLERECROM Eye Drops is indicated in adults and children for the relief and treatment of seasonal and perennial allergic conjunctivitis.

4.2 Posology and method of administration

Topical ophthalmic administration in adults and children: One or two drops in each eye four times a day.
Or as directed by the Physician.

Method of Administration

- For ocular use only.
- Not for injection.
- Do not touch tip of the vial to finger or to eye(s)/eyelids or to any other surface since this may contaminate the solution. Keep the bottle tightly closed when not in use.
- If eye irritation occurs, discontinue the use and consult the Physician.
- Contact lenses should be removed before instillation of the eye drops and may be reinserted after 15 minutes.
- If more than one topical ophthalmic medicinal product is being used, the medicinal products should be instilled 5 to 15 minutes apart. Eye ointments should be administered last.
- Discard unused portion of eye drop, if any, after one month of first opening the vial (even though expiry date is longer).
- Follow the directions mentioned on the container label.
- Us the solution within one month after opening the vial.

4.3 Contraindications

ALLERCROM Eye Drops are contraindicated in patients with known hypersensitivity to Cromolyn Sodium (also called as sodium cromoglicate) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Discard any remaining contents four weeks after opening the bottle.

Benzalkonium chloride (as preservative): As with other ophthalmic solutions containing benzalkonium chloride, soft contact lenses should not be worn during the treatment period.

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.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised.

Patients should be monitored in case of prolonged use.

Cromolyn sodium can be used prophylactically. Patients should seek advice before they discontinue use of the product.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy

As with all medication, caution should be exercised especially during the first trimester of pregnancy. Cumulative experience with sodium cromoglicate suggests that it has no adverse effects on fetal development. It should be used in pregnancy only where there is a clear need.

Breast feeding

It is not known whether sodium cromoglicate is excreted in human breast milk but, on the basis of its physicochemical properties, this is considered unlikely. There is no information to suggest the use of sodium cromoglicate has any undesirable effects on the baby.

Fertility

In rats, cromolyn sodium showed no evidence of impaired fertility. No data avaialable in human.

4.7 Effects on ability to drive and use machines

As with all eye drops, instillation of these eye drops may cause a transient blurring of vision. Patients are advised not to drive or operate machinery if affected, until their vision returns to normal..

4.8 Undesirable effects

Eye disorder: Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been reported rarely.

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.

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yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose
No action other than medical observation should be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals; Other antiallergics.
ATC code: SO1GX01

Mechanism of Action
Cromolyn sodium inhibits the degranulation of sensitised mast cells which occurs after exposure to specific antigens. Cromolyn sodium acts by inhibiting the release of histamine and various membrane derived mediators from the mast cell.

Pharmacodynamic Effects
This product exerts its effect locally in the eye.
Cromolyn sodium has demonstrated the activity *in vitro* to inhibit the degranulation of non-sensitised rat mast cells by phospholipase A and subsequent release of chemical mediators. Cromolyn sodium did not inhibit the enzymatic activity of released phospholipase A on its specific substrate. Cromolyn sodium has no intrinsic vasoconstrictor or antihistamine activity.

5.2 Pharmacokinetic properties
Cromolyn sodium is poorly absorbed. When multiple doses of cromolyn sodium ophthalmic solution are instilled into normal rabbit eyes, less than 0.07% of the administered dose of cromolyn sodium is absorbed into the systemic circulation (presumably by way of the eye, nasal passages, buccal cavity and gastrointestinal tract). Trace amounts (less than 0.01%) of the cromolyn sodium does penetrate into the aqueous humour and clearance from this chamber is virtually complete within 24 hours after treatment is stopped.
In normal volunteers, analysis of drug excretion indicates that approximately 0.03% of cromolyn sodium is absorbed following administration to the eye.
Cromolyn sodium is not metabolised.

5.3 Preclinical safety data
Non-clinical data reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Disodium Edetate, Sodium Chloride, Benzalkonium Chloride, Polysorbate 80, Water for Injection

6.2 Incompatibilities
None known

6.3 Shelf life
24 months.

6.4 Special precautions for storage
Store below 30°C. Protect from direct sunlight.

6.5 Nature and contents of container
5 ml solution in 5 ml LDPE vial with HIPS cap packed in a carton with pack Insert.

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.

Handling of the container:

- Wash your hands
- Remove the cap from the bottle.
- Tilt your head back.
- Squeeze one or two drops inside the lower lid without touching your eye, Close your eye.
- Wipe away any excess liquid from the eyes with a clean tissue.
- Always put the cap back on the bottle as soon as you have used it and repeat in the other eye.

7. MARKETING AUTHORISATION HOLDER
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8. MARKETING AUTHORISATION NUMBER(S)
04965/07155/REN/2019

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION
Feb 04, 2020

10. DATE OF REVISION OF THE TEXT
August 2023