SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cromsol® 2 % eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cromolyn Sodium 100 mg (for 5ml)

Excipients with known effect: benzalkonium chloride (preservative)
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Cromsol®2% is only used in prevention of ophthalmic allergies, more specifically, pollen conjunctivitis, seasonal conjunctivitis and marginal keratoconjunctivitis.

4.2. Posology and method of administration

This medicine is for ocular use only

Posology:
Adults and children: 1-2 drops in each eye 4 times a day.

Due to the preventive action of Cromsol®2%, the continuation of the treatment is important. When the treatment is discontinued, it is likely that the symptoms reoccur if the patient is still exposed to the stimuli responsible for the allergy.
Although some improvement can be obtained as of the first day of treatment, the beneficial effect will sometimes be reached, for the most severe cases, only after several weeks.

Mode of administration
Patients should be advised to:
1. wash hands thoroughly before instillation,
2. avoid contact of the tip of the bottle with the eye /eyelids,
3. instill 1 drop of eye drops in solution into the conjunctival sac tip of the diseased eye by looking up and slightly pulling the lower eyelid down, recap the bottle thoroughly after use.

4.3. Contraindications

Hypersensitivity to cromolyn sodium or to any of the components of eye drops listed in section 6.1 or residues.

4.4. Special warnings and precautions for use

After instillation the following measures should be taken in order to avoid systemic absorption:
-keep the eyelid closed during two minutes.
-close the lachrymal canal with the finger for two minutes.

In case of no improvement or if the symptoms persist, ask for medical advice.
CROMSOL® 2% contains benzalkonium chloride
Benzalkonium chloride can be adsorbed by soft contact lenses and change their color.
Remove contact lenses before application and wait at least 15 minutes before putting them back on.

Excipients with known effect
CROMSOL® 2% contains benzalkonium chloride
Based on the limited data available, the adverse reaction profile in children is similar to the adult profile.
However, a stronger reaction to a given stimulus is usually observed in children than in adults.
Irritation can affect treatment adherence in children.
Benzalkonium chloride is known to cause eye irritation, dry eye syndrome and can affect the tear film and corneal surface.
Should be used with caution in patients with dry eye and those at risk of corneal damage.
Patients should be monitored for prolonged use.

4.5. Interaction with other medicinal products and other forms of interaction

In case of concomitant treatment with another eye drop solution, wait for 15 minutes between the instillations.

4.6. Pregnancy, breast-feeding and fertility

There are no sufficient data demonstrating the safety of cromoglicate during pregnancy and lactation in humans.
It is recommended not to use Cromsol®2% during pregnancy and lactation.

4.7. Effects on ability to drive and use machines

CROMSOL®2%should be used with caution if any vision disorder occurs.
A transient visual disturbance can occur after usingCROMSOL®2%.
In that case, it is recommended to the patient not to drive or use dangerous machines until normal vision has reappeared.

4.8. Undesirable effects

Hypersensitivity reactions.
Transient stinging or burning sensation.
Transient vision trouble just after use of the drops

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization 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.

4.9. Overdose

In the event of a cromolyn sodium overdose, no toxic effect has been reported.
In case of excessive local administration, copiously wash with sterile physiologic serum.
Medical observation should suffice.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Anti-allergic,
ATC code: S01GX01

The solution exerts its effect locally in the eye. Cromolyn Sodium has been shown to inhibit the degranulation of sensitized mast cells containing inflammation mediators including vasoactive substances such as histamine, serotonin, and prostaglandins as well as eosinophil and neutrophil chemotactic factors. The result of this action is the inhibition of the immediate and delayed reactions following the allergic and other stimuli.

5.2. Pharmacokinetic properties

After instillation into the eye, the biggest part of the dose passes, through the mouth cavity, in the gastrointestinal tract and is later eliminated, mostly unchanged. A small quantity is absorbed in the systemic circulation (plasma levels normally below to 0.02 % of the dose) and then excreted unchanged in the urine and bile.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium chloride, edetate disodium, benzalkonium chloride, polysorbate 80, water for injections.

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 months
Do not use eye drops for more than 30 days after the bottle first opening

6.4. Special precautions for storage

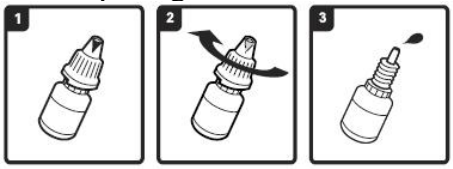
Store at room temperature (below 30°C). . Keep the bottle in the outer carton away from light.

6.5. Nature and contents of container

CROMSOL® 2% is available in a 5 ml transparent bottle of low-density polyethylene with white low-density polyethylene cap.

6.6. Special precautions for disposal and other handling

Bottle opening:



1. Place the cap, which has a tip, on the top of the bottle
2. Screw the cap while pressing it to pierce the bottle.
3. Dispensing the drops by applying gentle pressure to the bottle.
   Replace the cap after each use.

3. CATEGORY OF DISTRIBUTION

☒ Over-the counter medicine ☐ Prescription only medicine

4. MARKETING AUTHORISATION HOLDER:

Exphar sa
Zoning de Nivelles Sud, Zone II
Av. Thomas Edison 105 – 1402 Thines
Belgium

5. MANUFACTURER

AHLCON PARENTERALS (INDIA) LIMITED
SP-917-918, Phase-III, Ind Area, Bhiwadi-301019,
District Alwar (Rajasthan), India

6. UPDATE DATE

November 2022.