SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cromsol® 2 % eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For 5 ml:
Sodium cromoglicate 100 mg

Excipients: benzalkonium chloride solution (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 is only used in prevention of ophthalmic allergies, more specifically, pollen conjunctivitis, seasonal conjunctivitis and marginal keratoconjunctivitis.

4.2. Posology and method of administration

Adults and children: 1-2 drops in each eye 4 times a day.
Due to the preventive action of Cromsol, 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.
For the bottle opening instructions, see section 6.6.

4.3. Contraindications

Hypersensitivity to sodium cromoglicate or to any of the components.

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 during two minutes.
Do not inject nor swallow.
Do not exceed the recommended dose.
In case of no improvement or if the symptoms persist, ask for medical advice.
Carefully wash hands before performing instillation.
Avoid any contact between the nozzle and the eye or eyelid.
Recap the bottle after use.
The wearing of contact lenses is not recommended during the treatment.

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 and lactation

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

4.7. Effects on ability to drive and use machines

Sodium cromoglicate should be used with caution if any vision disorder occurs.
A transient visual disturbance can occur after using sodium cromoglicate.
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 itching or burning sensation.
Transient visual disorder after instillation of the eye drops.

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.

4.9. Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Anti-allergics, ATC code: S01GX01
The solution exerts its effect locally in the eye. Sodium cromoglicate has been shown to inhibit the degranulation of vasoactive substances including histamine, serotonin and eosinophil and neutrophil chemotactic factors from sensitised mast cells. 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 solution, polysorbate 80, water for injections.

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store at room temperature (below 30°C). Protect from light. Do not use after one month after the bottle opening.

6.5. Nature and contents of container

The bottle is made of clear low density polyethylene.
Plastic cap of white low density polyethylene.
Bottle of 5 ml.

6.6. Special precautions for disposal and other handling

Bottle opening:

1. With the spike: tighten the cap on the nozzle.
2. The spike in the cap will pierce the tip of the bottle.
3. Dispense drops with gentle pressure. Replace the cap after every use.

7. CATEGORY OF DISTRIBUTION

☒ Over-the counter medicine ☐ Prescription only medicine

8. MARKETING AUTHORISATION HOLDER:

Exphar sa
Zoning de Nivelles Sud, Zone 2
Av. Thomas Edison 105 – 1402 Thines
Belgium

9. MANUFACTURER

AHLCON PARENTERALS (INDIA) LIMITED

SP-918, Phase-III, Bhiwadi-301019,
Dist.: Alwar (Rajasthan), India

10. UPDATE DATE

January 2019