Summary of product characteristics

Epicrom 2%
Eye drops

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1. Name of the medicinal product:
Epicrom 2% Eye drops

2. Qualitative and quantitative composition:
Each ml contains:
Cromolyn sodium ..... 20 mg
For inactive ingredients see section 6.1

3. Pharmaceutical form:
Sterile Eye Drops

4. Clinical particulars:
4.1 Therapeutic indications:
Treatment of allergic conditions of the eye, including:
- Acute and chronic allergic conjunctivitis.
- Vernal keratoconjunctivitis.
- Hay Fever conjunctivitis.
- Giant papillary conjunctivitis.

4.2 Posology and method of administration:
Adults and children > 4 years of age:
1 – 2 Drops should be instilled in each eye, 4 – 6 times a day, at regular intervals.
Symptomatic response to therapy (decreased itching, tearing, redness, and discharge) is usually evident within a few days, but longer treatment for up to 6 weeks is sometimes required.
EPICROM should be used only during one month after opening.

4.3 Contraindications:
- Hypersensitivity to the product.
- Children below the age of 4 years; since safety and efficacy have not been established.

4.4 Special warnings and precautions for use:
- **EPICROM** should be used with caution in pregnancy and lactation; may be used only if the potential benfit justifies the potential risk.
- Once symptomatic improvement has been established, continue therapy for as long as needed to sustain improvement.
- Patients should avoid allowing the tip of the dispensing container to contact the eye(s) or surrounding structures to avoid bacterial contamination.
- Patients should be advised that:
- Effect of **EPICROM** is dependent on its administration at regular intervals, as directed.
- Do not wear soft contact lenses while using **EPICROM**.

4.5 Interaction with other medicinal products:
None.

4.6 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 foetal development. It should be used in pregnancy only where there is a clear need.
Lactation: 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.

4.7 Effects on ability to drive and use machines:
None.

4.8 Undesirable effects:
The most frequently reported side-effect is transient ocular stinging or burning upon instillation. Other side-effects may include dryness around the eye, puffiness, and irritation.

4.9 Overdose:
None.

5. Pharmacological properties:
5.1 Pharmacodynamic properties:

EPICROM (cromolyn sodium), a chromone derivative, acts as mast cell stabilizer. It inhibits the degranulation of sensitized mast cells that occurs after patient's exposure to specific antigens. **EPICROM** also acts by preventing the release of histamine and other mediators of inflammation from the sensitized mast cells through stabilization of mast-cell membranes.

5.2 Pharmacokinetic properties
It has been reported that approximately 0.03% of cromolyn is absorbed following administration to the eye. The drug is excreted unchanged in urine and bile.

6. Pharmaceutical particulars:
6.1 List of inactive ingredients:
Benzalkonium chloride, disodium edetate, polysorbate 80, water for injection.

6.2 Incompatibilities:
None known

6.3 Shelf life:
3 years.

6.4 Special precautions for storage:

Store at a temperature not exceeding 30°C. Not to be used after one month from opening.

6.5 Nature and contents of container:
EPICROM® Eye Drops 2%: 10 ml Plastic dropper bottle.

6.6 Special precautions for disposal and other handling:
Any unused medicine or waste material should be disposed of by taking to your local pharmacy.

7. Marketing authorization holder:
EIPICO

8. Date of revision of the text:
March 2021