GACROM

SODIUM CROMOGLICATE EYE DROPS BP 2.0 %w/v

Summary of Product Characteristics

Document type:	Summary of Product Characteristics
Document status:	Final
Release date:	20th Feb. 2019
Number of pages:	4 pages

1 NAME OF THE MEDICINAL PRODUCT

Sodium Cromoglicate Eye Drops 0.3 % w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:
Sodium Cromoglicate BP……... 2.0 %w/v
Benzalkonium Chloride USP (as preservatives)……. 0.01 %w/v
Aqueous Vehicle…… Q.S.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORMS

Eye Drops

4 CLINICAL PARTICULARS

4.1 Therapeutic Indication.

GACROM Eye Drops are for the prophylaxis and symptomatic treatment of acute allergic conjunctivitis, chronic allergic conjunctivitis and vernal kerato conjunctivitis.

4.2 Posology and method of administration.

Route of Administration:

For topical administration to the eye.

Adults, Children and the Elderly

One or two drops into each eye up to four times daily.

4.3 Contraindications

Known hypersensitivity to benzalkonium chloride, sodium cromoglycate or other constituents.

4.4 Special warnings and precaution for use.

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. GACROM Eye Drops contain benzalkonium chloride. Do not wear soft contact lenses during the period of use

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

None known

4.6 Pregnancy and Lactation.

Use in Pregnancy*:* GACROM Eye Drops should be used cautiously during pregnancy and lactation. The widespread use of sodium cromoglycate has yet to reveal any adverse effects to mother or child during pregnancy.

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

4.7 Effect on the ability to drive and use machine.

Transient stinging or blurred vision may occur on instillation. Do not drive or operate machinery until proper vision is restored.

4.8 Undesirable effect.

Transient stinging and burning may occur after instillation, other symptoms of local irritation have been reported rarely.

4.9 Overdose.

As sodium cromoglycate is absorbed only to a very limited extent from eye drops, no action other than medical observation should be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

Sodium cromoglycate has neither anti-histaminic or anti-inflammatory activity. Evidence suggests that sodium cromoglycate inhibits the release of mediators of the allergic reaction by stabilising the membranes of sensitised mast cells.

5.2 Pharmacokinetic properties.

Due to lipid insolubility, sodium cromoglycate is poorly absorbed following administration to the eye. In normal volunteers approximately 0.03% is systemically absorbed. Absorbed sodium cromoglycate is excreted unchanged in the bile and urine.

Trace amounts of sodium cromoglycate have been detected in the aqueous humor of rabbits for up to 24 hours after treatment.

5.3 Preclinical safety data.

The results of the studies do not add to the information needed by the prescriber, consequently, they are not repeated in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80	*BP*
Disodium Edetate	*BP*
Benzalkonium chloride	*USP*
Disodium Hydrogen Phosphate Dihydrate	*BP*
Water for Injection	*BP*

6.2 Incompatibilities

unknown

6.3 Shelf-life

36 months

6.4 Special precautions for storage

Do not store above 25ºC. Store in a dry place.

6.5 Nature and composition of immediate packaging

A clear, colourless to light yellow solution filled in 5 ml or 10 ml HDPE container pluged with dropper attachment plug, sealed with screw cap closure.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

None.

7 MARKETING AUTHORISATION HOLDER

8 MARKETING AUTHORISATION NUMBER(S)

9 AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

20th Feb 2019