PROFESSIONAL INFORMATION

SCHEDULING STATUS: S2

1. NAME OF THE MEDICINE

STOP-ALLERG EYE DROPS

2,0 % $^{w}/_{v}$ Eye drop, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:	
Sodium cromoglycate	20 mg

Excipient with known effect:

Preservative: Benzalkonium chloride solution 0,01 % $^{m}/_{v}$

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Eye drops, solution

A clear-colourless to clear-yellow liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Allergic conjunctivitis.

4.2 Posology and method of administration

Posology

Adults (including the elderly) and children: 1-2 drops into each eye 4 times daily.

STOP-ALLERG EYE DROPS should be used regularly to ensure optimal control of symptoms.

It is recommended that treatment is continued during the period of exposure to the allergen, even when free of symptoms.

Method of administration

For ophthalmic use only.

Care should be taken to avoid contamination of the contents during use.

Patient should be advised not to wear soft contact lenses during treatment with STOP-ALLERG EYE DROPS.

4.3 Contraindications

- Known hypersensitivity to sodium cromoglycate or any of the other excipients listed in 6.1.

4.4 Special warnings and precautions for use

- Where concomitant steroid and sodium cromoglycate treatment has rendered it possible to reduce the steroid dose, precautions must be taken to prevent a severe attack if/ when sodium cromoglycate is withdrawn from the treatment regime.
- Patients should be monitored in case of prolonged use.
- STOP-ALLERG EYE DROPS can be used prophylactically. Patients should seek advice before they discontinue use of STOP-ALLERG EYE DROPS.
- STOP-ALLERG EYE DROPS contains benzalkonium chloride as a preservative.
    - This medicine contains 0,24 g benzalkonium chloride 50 % solution in 1 litre which is equivalent to 0,01 % $^{m}/_{v}$.
    - As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride, preserved ophthalmological preparations cannot be excluded, regular ophthalmological examination is required.
    - Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.
    - Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Contact lenses should be removed before using this medicine and reinserted after 15 minutes.
    - Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Fertility: No available data

Pregnancy: STOP-ALLERG EYE DROPS should be used with caution during the first trimester of pregnancy as safety has not been established. Cumulative experience with sodium cromoglycate suggests that it has no adverse effects on foetal development.

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

4.7 Effects on ability to drive and use machines

Transient stinging or blurred vision may occur on instillation (see section 4.8). Do not drive or operate machinery until proper vision is restored.

4.8 Undesirable effects

a) Tabulated summary of adverse reactions

System Organ Class	***Frequency***	***Undesirable effect***
Immune System Disorders	Unknown	Hypersensitivity reactions (including headache, skin rash, bronchospasm, breathlessness, anaphylaxis).
Eye Disorders	Less frequent	Local irritation
	Unknown	Transient burning or stinging and blurring may occur after instillation.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA)

and eReporting platform (who- umc.org) found on SAHPRA website.

You may also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

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. In the event of accidental ingestion, symptomatic treatment is recommended. If a hypersensitive reaction occurs, withdraw treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: 15.4 Ophthalmic preparations (Others)

Pharmacotherapeutic group: Ophthalmologicals; other antiallergics

ATC code: SO1GX01

Sodium cromoglycate has no intrinsic vasoconstrictor or antihistamine activity.

In vitro and in vivo animal studies have shown that sodium cromoglycate inhibits the degranulation of sensitised mast cells which occurs after exposure to specific antigens. Sodium cromoglycate acts by inhibiting the release of histamine and various membrane-derived mediators from the mast cell. Sodium cromoglycate 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. Sodium cromoglycate did not inhibit the enzymatic activity of released phospholipase A on its specific substrate. Sodium cromoglycate has no intrinsic vasoconstrictor or antihistamine activity.

5.2 Pharmacokinetic properties

Sodium cromoglycate is poorly absorbed. When multiple doses of Sodium cromoglycate ophthalmic solution are instilled into normal rabbit eyes, less than 0,07 % of the administered dose of Sodium cromoglycate 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 Sodium cromoglycate

dose 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 medicine excretion indicates that approximately 0,03 % of Sodium cromoglycate is absorbed following administration to the eye

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Disodium edetate
- Purified water
- Benzalkonium chloride solution 0,01% m/v

6.2 Incompatibilities

None.

6.3 Shelf life

Unopened: 36 months

First opening: 30 days

6.4 Special precautions for storage

Store at or below 25 °C. Protect from direct light.

Discard 30 days after opening the bottle

6.5 Nature and contents of container

White bottle with tips and caps (tamper proof screw) of 10 ml and 15 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

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Midrand, 1685

Customer Care: 0860 ADCOCK/ 232625

8. REGISTRATION NUMBER

W/15.4/430

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20 November 1989

10. DATE OF REVISION OF THE TEXT

27 March 2025

Namibia: NS2 90/15.4/00564