SCHEDULING STATUS

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1 NAME OF THE MEDICINE

CROMOBEX 2,0 % w/v eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL of CROMOBEX contains sodium cromoglycate dihydrate equivalent to 20 mg sodium cromoglycate.

Excipients with known effects:

Contains preservative: 0,01 % m/v benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Clear, colourless to slightly yellow solution, practically free from visible particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Allergic conjunctivitis.

4.2 Posology and method of administration

Adults and children:

Instil 1 or 2 drops into each eye 4 times daily.

It is important that the regular administration of CROMOBEX is maintained in the prevention and treatment of allergic conjunctivitis as therapy is essentially prophylactic.

4.3 Contraindications

Hypersensitivity to sodium cromoglycate, benzalkonium chloride or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The solution should be discarded 1 month after first opening the bottle or if any turbidity develops.

CROMOBEX should not be used if the bottle has been opened prior to receipt.

Patients should also be instructed that ocular solutions, if handled improperly can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions. Patients should also be advised that if they develop any intercurrent ocular condition (e.g. trauma, ocular surgery or infection), they should immediately seek their medical practitioner's advice concerning the continued use of CROMOBEX. There have been reports of baterial keratitis associated with the use of topical ophthalmic products.

Where concomitant steroid and CROMOBEX treatment has rendered it possible to reduce the steroid dose, precautions must be taken to prevent a severe attack if/when CROMOBEX is withdrawn from the treatment regime.

CROMOBEX contains benzalkonium chloride

This medicine contains 0,00306 mg benzalkonium chloride in each drop (0,0306 mL) which is equivalent to 0,1 mg/mL.

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. Patients should be monitored in case of prolonged use.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Soft contact lenses should not be worn during the treatment period. The lenses should be removed before instillation of the drops and not reinserted earlier than 15 minutes after use.

Burning or stinging may occur following instillation of the drops.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established.

Breastfeeding

It is not known whether sodium cromoglicate is excreted in human breast milk, but based on its physicochemical properties this is considered unlikely. Therefore, caution should be exercised when CROMOBEX eye drops are administered to breastfeeding mothers.

Fertility

It is not known whether sodium cromoglicate has any effect on fertility.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Immune system disorders:

Frequency unknown: anaphylaxis.

Nervous system disorders:

Frequency unknown: headache.

Eye disorders:

Less frequent: transient stinging and blurring of eyes after installation, eye irritation.

Respiratory, thoracic and mediastinal disorders:

Frequency unknown: bronchospasm, breathlessness.

Skin and subcutaneous tissue disorders:

Frequency unknown: skin rash.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of CROMOBEX is important. It allows continued monitoring of the benefit/risk balance of CROMOBEX. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

As sodium cromoglicate 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: A 15.4 Ophthalmic preparations (other)

Pharmacotherapeutic group: Ophthalmologicals; Other antiallergics

ATC code: SO1GX01

Sodium cromoglycate is an anti-allergic medicine that acts mainly by inhibiting release of inflammatory mediators.

5.2 Pharmacokinetic properties

Absorption

Due to lipid insolubility, sodium cromoglicate is poorly absorbed following administration to the eye. In normal volunteers, analysis of medicine excretion indicates that approximately 0,03 % of sodium cromoglicate is absorbed following administration to the eye.

Distribution

Trace amounts (less than 0,01 %) of the sodium cromoglicate have been detected in the aqueous humour of rabbits for up to 24 hours after treatment.

Elimination

Absorbed sodium cromoglicate is excreted unchanged in the bile and urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride, Disodium edetate, Disodium hydrogenphosphate dodecahydrate, Sodium chloride, Sodium dihydrogen phosphate dihydrate, Sorbitol liquid, Water for injections.

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened: 36 months.

Opened: Discard any unused contents 4 weeks after opening.

Store at or below 25 °C.

6.4 Special precautions for storage

Protect from light.

6.5 Nature and contents of container

White polyethylene dropper bottle containing 10 mL solution.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

iPharma (Pty) Ltd

124 Elevation Avenue, Randjesfontein

Midrand, 1683, South Africa

8 REGISTRATION NUMBER

29/15.4/0382

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

June 1996

10 DATE OF REVISION OF THE TEXT

14 April 2023

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iPharma