New Zealand Datasheet

1 PRODUCT NAME
Rexacrom eye drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Sodium cromoglycate 2% w/v

3 PHARMACEUTICAL FORM
A sterile, clear colourless to pale yellow, preserved, solution containing 2% w/v of sodium cromoglycate in a capped vial for ophthalmic administration.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
For the prevention and treatment of allergic conjunctivitis (including seasonal allergic conjunctivitis, perennial allergic conjunctivitis and vernal kerato conjunctivitis).

4.2 Dose and method of administration
Adults (including the elderly) & Children
One or two drops of solution into each eye four times daily.

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

4.3 Contraindications
Rexacrom eye drops are contraindicated in patients with known hypersensitivity to sodium cromoglycate, or any of the other constituents.

4.4 Special warnings and precautions for use
As with all ophthalmic preparations containing benzalkonium chloride, patients should be advised not to wear soft contact lenses during treatment with Rexacrom eye drops.

4.5 Interaction with other medicines and other forms of interaction
Sodium cromoglycate has been used in many animal drug interaction studies and for the treatment of a variety of indications in man. No evidence of interaction with other drugs has been observed.

4.6 Fertility, pregnancy and lactation
Use in pregnancy
Category A. Cumulative experience with sodium cromoglycate suggests that it has no effects on foetal development. It should be used in pregnancy only if there is a clear need.

Use in lactation
On the basis of animal studies and its physicochemical properties, sodium cromoglycate is considered unlikely to pass into human breast milk. There is no information to suggest that use of sodium cromoglycate by nursing mothers has any undesirable effects on the baby.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

Transient stinging or blurring of vision may occur on instillation of the drops. Do not drive or use machinery until normal vision is restored.

4.8 Undesirable effects

Transient burning and stinging may occur after administration of Rexacrom eye drops into the eye.

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. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

Medical observation should be the only action required.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals; Other antiallergics, ATC Code: S01GX01

Sodium cromoglycate inhibits the degranulation of mast cells which become sensitised after exposure to specific antigens as shown in several in vitro and in vivo animal studies. Sodium cromoglycate inhibits the release of histamine and various membrane derived mediators from the mast cell.

In vitro studies have demonstrated that sodium cromoglycate inhibits the degranulation of non-sensitised rat mast cells by phospholipase A and subsequently prevents the 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

Analysis of urinary excretion of the drug in normal volunteers demonstrated that 0.03%, a very small proportion of the dose, is absorbed systemically following administration into the eye. Most of the large remaining proportion is drained through the nasolacrimal duct into the nasal cavity, and eventually into the gastrointestinal tract. Some absoroption also occurs through the eye and nasal and buccal mucosa. Absorption from the gastrointestinal tract is low. The drug has a high systemic clearance (plasma clearance 7.9 ± 0.9mL/min/kg) so that any absorbed drug is rapidly cleared from the circulation and accumulation does not occur.

Trace amounts (less than 0.01%) of Sodium cromoglycate penetrate into the aqueous humour. Clearance from this chamber is virtually complete within 24 hours after treatment is stopped.

Following topical ophthalmic administration of sodium cromoglycate to normal rabbit eyes less than 0.07% of the dose is absorbed into the systemic circulation. Studies of the rabbit also indicate that the drug does not accumulate in the eye.

Sodium cromoglycate is not metabolized and is excreted unchanged in the bile and urine in appropriately equal proportions.

Sodium cromoglycate is reversibly bound to plasma proteins (>65%).

5.3 Preclinical safety data
Animal studies have shown that sodium cromoglycate has a very low order of local or systemic toxicity.

Pharmaceutical Precautions
6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Benzalkonium chloride 0.01% w/v, Disodium edetate dihydrate, Disodium hydrogen phosphate, Polysorbate 80, Water for injection

6.2 Incompatibilities
Benzalkonium chloride may be deposited in and is known to discolour soft contact lenses. These lenses should therefore be removed before instillation of the eye drops and not reinserted earlier than 15 minutes after use.

6.3 Shelf life
Shelf life is 42 months from manufacture.

6.4 Special precautions for storage
Store below 25°C. Protect from direct sunlight.
Discard any remaining contents four weeks after first opening the vial.
Discard any remaining contents after the expiry date on the vial.

6.5 Nature and contents of container
5mL LDPE dropper bottle.

6.6 Special precautions for disposal and other handling
Not applicable.

7 MEDICINE SCHEDULE
Pharmacy Medicine

8 SPONSOR
REX Medical Ltd
PO Box 18-119
Glen Innes 1743
AUCKLAND.

Ph (09) 574 6060
Fax (09) 574 6070

9 DATE OF FIRST APPROVAL
28 September 2006

10 DATE OF REVISION OF THE TEXT
19 September 2018

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.7	Section added
4.8	Reporting of adverse events added
4.9	Poison information centre contact added
6.2	Section added