

New Zealand Datasheet

Name of Medicine

Rexacrom eye drops
Sodium cromoglycate 2% w/v

Presentation

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

Uses

Actions

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.

Pharmacokinetics

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 absorption 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 $7.9 \pm 0.9 \text{ mL/min/kg}$) 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%).

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

Indications

For the prevention and treatment of allergic conjunctivitis (including seasonal allergic conjunctivitis, perennial allergic conjunctivitis and vernal kerato conjunctivitis).

Dosage and 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.

Contraindications

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

Warnings and Precautions

As with all ophthalmic preparations containing benzalkonium chloride, patients should be advised not to wear soft contact lenses during treatment with Rexacrom eye drops.

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.

Adverse Effects

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

Interactions

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.

Overdosage

Medical observation should be the only action required.

Pharmaceutical Precautions

Instructions for Use/Handling

Discard any remaining contents four weeks after first opening the vial.

Shelf life

Discard any remaining contents after the expiry date on the vial.

Special precautions for storage

Store below 25°C. Protect from direct sunlight.

Medicine Classification

Pharmacy Only Medicine.

Package Quantities

5mL bottle.

Further Information

Sodium Cromoglycate Eye Drops contains 0.01% w/v benzalkonium chloride as a preservative as do several other products for ophthalmic use.

Name and Address

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Date of Preparation

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