

CROMOLUX Eye Drops

Sodium cromoglycate 2%.

Presentation

A sterile, clear, colourless preserved, aqueous solution containing 2% w/v of sodium cromoglycate in a dropper bottle for ophthalmic administration.

Uses

Actions

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 of inflammation from mast cells. Sodium cromoglycate has no intrinsic vasoconstrictor or antihistaminic activity.

Pharmacokinetics

Absorption:

In normal volunteers analysis of urinary excretion of the drug indicates that only a very small proportion of the dose (0.03%) is absorbed following administration to the eye. Most of the dose will drain into the nasal cavity and eventually into the gastrointestinal tract from where absorption is also low. The drug has a high systemic clearance (plasma clearance 7.9 ± 0.9 ml/min/kg) so that any absorbed drug is rapidly cleared from the circulation and accumulation does not occur.

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.

Excretion:

Sodium cromoglycate is reversibly bound to plasma proteins (>65%) and is not metabolised, being excreted unchanged in the bile and urine in appropriately equal portions.

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) and children:

One or two drops of solution into each eye four to six times a day at regular intervals. The use of CROMOLUX for about a week before the expected allergy season may assist in reducing symptoms associated with eye allergies. Therapy should be continued for as long as needed to sustain relief.

Contraindications

CROMOLUX is 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 CROMOLUX Eye Drops.

Use in Pregnancy and Lactation

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.

Lactation:

On the basis of animal studies and its physiochemical 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 stinging and burning may occur after instillation of CROMOLUX Eye Drops.

Interactions

Sodium cromoglycate has been used for the treatment of a variety of indications in man, and it has been the subject of many animal drug interaction studies. No evidence of interaction with other drugs has been observed.

Overdosage

No action other than medical observation should be necessary.

Pharmaceutical Precautions

Eye Drops

Store below 25°C. Protect from direct sunlight. Discard any remaining contents four weeks after first opening the bottle.

Medicine Classification

Pharmacy Medicine.

Package Quantities

10ml bottle

Further Information

In common with several other products for ophthalmic use, CROMOLUX Eye Drops contains 0.01% w/v benzalkonium chloride as a preservative.

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Date of Preparation

December 2005