CROMAL Eye Drops (Sodium cromoglycate 2%)

**Composition**

Sodium Cromoglycate, IP ............... 2% w/v  
Benzalkonium Chloride, NF (preservative) .... 0.01% w/v  
Sterile aqueous vehicle ............... q.s.

**Dosage Form**

Ophthalmic solution

**Pharmacology**

**Pharmacodynamics**

*In vitro* and *in vivo* animal studies have shown that sodium cromoglycate inhibits the degranulation of sensitized mast cells, which occurs after exposure to specific antigens. Sodium cromoglycate acts by inhibiting the release of histamine and SRS-A (slow-reacting substance of anaphylaxis) from mast cells. Sodium cromoglycate has demonstrated activity, *in vitro*, to inhibit the degranulation of non-sensitized 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, antihistaminic or anti-inflammatory activity.

**Pharmacokinetics**

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 eyes, nasal passages, buccal cavity and gastrointestinal tract). Trace amounts (less than 0.01%) of sodium cromoglycate does 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 drug excretion indicates that approximately 0.03% of sodium cromoglycate is absorbed following administration to the eyes.

**Indications**

Sodium cromoglycate ophthalmic solution is indicated for the symptomatic treatment of vernal keratoconjunctivitis, vernal conjunctivitis and vernal keratitis.

**Dosage And Administration**

One to two drops in each eye, four to six times in a day at regular intervals, or as indicated by the doctor.
**Contraindications**

The product is contraindicated in patients who have shown hypersensitivity to sodium cromoglycate, benzalkonium chloride or to any of the other ingredients.

**Warnings And Precautions**

▶ **General**

Patients may experience a transient stinging or burning sensation following instillation of sodium cromoglycate ophthalmic solution. The recommended frequency of administration should not be exceeded.

Discard any remaining contents 4 weeks after opening the bottle.

As with other ophthalmic solutions containing benzalkonium chloride, soft contact lenses should not be worn during the treatment period.

Sodium cromoglycate can be used prophylactically. Patients should seek advice before they discontinue the use of the product.

As with all eye drops, instillation of these eye drops may cause a transient blurring of vision.

▶ **Drug Interactions**

None known.

▶ **Pregnancy**

Pregnancy Category B

As with all medication, caution should be exercised, especially during the first trimester of pregnancy. Cumulative experience with sodium cromoglycate suggests that it has no adverse effects on foetal development. It should be used in pregnancy only where there is a clear need.

▶ **Lactation**

It is not known whether sodium cromoglycate is excreted in human breast milk, but, on the basis of its physicochemical properties, this is considered unlikely. There is no information to suggest that the use of sodium cromoglycate has any undesirable effects on the baby. Because many drugs are excreted in human milk, caution should be exercised when sodium cromoglycate ophthalmic solution is administered to a nursing mother.

▶ **Pediatric Use**

Safety and efficacy of sodium cromoglycate ophthalmic solution in children younger than 4 years of age has not been established.

▶ **Geriatric Use**

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

**Undesirable Effects**

The most frequently reported undesirable effects are transient ocular stinging or burning upon instillation. Other symptoms of local irritation have been reported rarely.

The following adverse reactions have been reported as infrequent events. It is unclear whether they are attributed to the drug: conjunctival injection; watery eyes; itchy eyes; dryness around the eye; puffy eyes; eye irritation; and styes.
Immediate hypersensitivity reactions have been reported rarely and include dyspnoea, oedema and rash.

**Overdosage**

No action other than medical observation should be necessary.

**Incompatibility**

None known.

**Shelf-Life**

3 years.

**Storage And Handling Instructions**

Store in a cool, dark place.

**Packaging Information**

CROMAL Eye Drops: Vial of 5 ml

**Information For Patients**

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