OPTICROM EYE DROPS

1 TRADE NAME OF THE MEDICINAL PRODUCT

Opticrom Eye Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium cromoglicate 2.0% w/v.
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, Solution (Eye Drops).
A clear colourless or pale yellow liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Preventive treatment for all types of allergic conjunctivitis.

4.2 Posology and Method of Administration

Topical Ophthalmic administration

One or two drops in each eye four times a day or as indicated by the doctor.

Elderly

No current evidence for alteration of the dose.

4.3 Contraindications

The product is contraindicated in patients who have shown hypersensitivity to Sodium cromoglicate, Benzalkonium chloride or Disodium edetate.

4.4 Special Warnings and Special Precautions for Use

Discard any remaining contents four weeks after opening the bottle.

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

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

4.5 Interactions with Other Medicaments and Other Forms of Interaction

None known.

4.6 Pregnancy and Lactation

Pregnancy
As with all medication, caution should be exercised especially during the first trimester of pregnancy. Cumulative experience with Sodium cromoglicate 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 cromoglicate is excreted in human breast milk but, on the basis of its physicochemical properties, this is considered unlikely. There is no information to suggest the use of Sodium cromoglicate has any undesirable effects on the baby.

4.7 Effects on Ability to Drive and Use Machines

As with all eye drops, instillation of these eye drops may cause a transient blurring of vision or cause local irritation that could impact driving or operating machinery. Do not drive or operate machinery if affected.

4.8 Undesirable Effects

Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been reported rarely.
Hypersensitivity reactions have been reported extremely rarely.

4.9 Overdose

No action other than medical observation should be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Opthalmologicals; Other antiallergics, ATC Code: S01GX01.

In vitro and *in vivo* animal studies have shown that Sodium cromoglicate inhibits the degranulation of sensitised mast cells which occurs after exposure to specific antigens. Sodium cromoglicate acts by inhibiting the release of histamine and various membrane derived mediators from the mast cell.

Sodium cromoglicate has demonstrated the activity *in vitro* to inhibit the degranulation of non-sensitised rat mast cells by phospholipase A and subsequent release of chemical mediators. Sodium cromoglicate did not inhibit the enzymatic activity of released phospholipase A on its specific substrate.

Sodium cromoglicate has no intrinsic vasoconstrictor or antihistamine activity.

5.2 Pharmacokinetic Properties

Sodium cromoglicate is poorly absorbed. When multiple doses of Sodium cromoglicate ophthalmic solution are instilled into normal rabbit eyes, less than 0.07% of the administered dose of Sodium cromoglicate is absorbed into the systemic circulation (presumably by way of the eye, nasal passages, buccal cavity and gastrointestinal tract). Trace amounts (less than 0.01%) of the Sodium cromoglicate 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 cromoglicate is absorbed following administration to the eye.

5.3 Preclinical Safety Data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Disodium edetate, Benzalkonium chloride, Water for injection.

6.2 Incompatibilities

None known.

6.3 Special Precautions for Storage

Store below 30^{o}C and protect from direct sunlight. Discard any remaining contents four weeks after opening.

7 MARKETING AUTHORISATION HOLDER

Sanofi-aventis Israel ltd.

8 MANUFACTURER

Sanofi Winthrop Industrie, France.