PRODUCT INFORMATION
OPTICROM EYE DROPS

TGA Approved 18 August 1986

COMPOSITION:

Sodium cromoglycate 2% w/v in an aqueous solution preserved with benzalkonium chloride.

PHYSICAL AND CHEMICAL CHARACTERISTICS:

Sodium cromoglycate is a white, odourless, hygroscopic, crystalline powder, tasteless at first with a slightly bitter aftertaste.

Soluble 1 in 20 of water; practically insoluble in alcohol and chloroform.

Molecular weight 512.3 $\mathbf{C_{23}H_{14}Na_2O_{11}}$

PHARMACOLOGY:

In immediate (Type 1) allergic reactions, the union of antigen and reaginic (IgE) antibody on sensitised mast cells leads to the release of spasmogens and other mediators of the anaphylactic reaction. Sodium cromoglycate appears to block a step in the chain of events triggered by this union, thereby preventing immediate conjunctival reactions.

PHARMACOKINETICS:

Sodium cromoglycate is very poorly absorbed from the gastrointestinal tract when taken orally. After inhalation of the drug in powder form it is rapidly absorbed in the lung. From the lung it is cleared rapidly and excreted unchanged in the urine and bile. Approximately 97% of the inhaled dose is cleared at a rate corresponding to a half life of 0.6 hours; the remainder is cleared at a slow rate corresponding to a half life of 1.5 hours. In man sodium cromoglycate is excreted in approximately equal amounts in the urine and bile. No evidence of metabolites has been detected. No data available on protein binding. In one study of absorption from eye drops a maximum of 0.01% of a daily dose was excreted in the urine over 24 hours.

INDICATIONS:

For the treatment of allergic conjunctivitis, and vernal keratoconjunctivitis.

CONTRAINDICATIONS:

- Hypersensitivity to sodium cromoglycate
- Hypersensitivity to benzalkonium chloride
- Hypersensitivity to other constituents

WARNING:

Soft contact lenses should be removed during treatment with Opticrom due to possible interaction with benzalkonium chloride. Wear may be resumed within a few hours of discontinuation of Opticrom.

PRECAUTIONS:

Renal and hepatic impairment.
Although normal dosage is indicated in renal or hepatic impairment the biliary and renal routes of excretion emphasise that the drug should nevertheless be used with caution in such patients.

Driving a vehicle or performing other potentially hazardous tasks

Instillation of Opticrom eye drops may cause local irritation that could impact driving or operating machinery.

Use in pregnancy
Category A of Australian Categorisation of Risk of Drug Use in Pregnancy.

It is an accepted medical principle to be cautious of using any medication during the first trimester of pregnancy. No teratogenic effects have been attributed to sodium cromoglycate. Opticrom eye drops should be used in pregnancy only if there is a clear need.

Use in lactation
Due to very poor absorption of sodium cromoglycate from the eye it is unlikely that the use of Opticrom would preclude breast feeding.

ADVERSE REACTIONS:

Swelling of the eyelids or the conjunctiva have been reported occasionally, due to hypersensitivity to benzalkonium chloride.
Transient stinging and burning may occur after instillation of Opticrom eye drops. Other symptoms of local irritation have been reported rarely. Hypersensitivity reactions have been reported extremely rarely.

DOSAGE AND ADMINISTRATION:

By instillation into the conjunctival sac, 1 or 2 drops into each eye four/six times daily for both children and adults.

PRESENTATION:

Eye drops 2%: 10mL (dropper bottle).

STORAGE:

When stored below 30□C the shelf life is 2 years. Discard contents 4 weeks after opening the bottle.

POISONS SCHEDULE:

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SPONSOR: Aventis Pharma Pty Ltd
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