

AUSTRALIAN PRODUCT INFORMATION

OPTICROM (SODIUM CROMOGLYCATO)

1 NAME OF THE MEDICINE

OPTICROM EYE DROPS
sodium cromoglycate 2% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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 $C_{23}H_{14}Na_2O_{11}$

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Eye drops

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the treatment of allergic conjunctivitis, and vernal keratoconjunctivitis.

4.2 DOSE AND METHOD OF ADMINISTRATION

Dosage

1 or 2 drops into each eye four/six times daily for both children and adults.

Method of administration

By instillation into the conjunctival sac.

4.3 CONTRAINDICATIONS

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

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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.

Use in hepatic impairment

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

Use in renal impairment

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

Use in elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Drug interactions have not been systematically studied between Opticrom eye drops and other drugs. However, no interactions are known to date.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

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.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at <http://www.tga.gov.au/reporting-problems> .

4.9 OVERDOSE

For general advice on overdose management, contact the Poisons Information Centre, telephone number 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

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.

Clinical trials

Not Applicable

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Sodium cromoglycate is very poorly absorbed from the gastrointestinal tract when taken orally.

Distribution

After inhalation of the drug in powder form it is rapidly absorbed in the lung.

Metabolism

From the lung it is cleared rapidly and excreted unchanged in the urine and bile.

Excretion

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.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Disodium edetate
Purified water
Benzalkonium chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

18 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Storage conditions

Store below 25°C. Protect from direct sunlight.
Discard contents 4 weeks after opening the bottle.

6.5 NATURE AND CONTENTS OF CONTAINER

Container type

Dropper bottle

Pack sizes

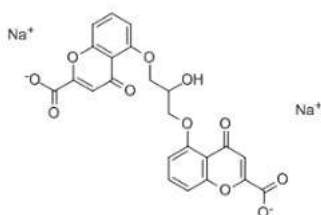
10mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



CAS number

15826-37-6

7 MEDICINE SCHEDULE (POISONS STANDARD)

Pharmacy Medicine (Schedule 2)

8 SPONSOR

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Australia

9 DATE OF FIRST APPROVAL

18 August 1986

10 DATE OF REVISION

28 March 2018

Summary table of changes

Section Changed	Summary of new information
6.3	Update to the shelf life
6.4	Update to the storage conditions
7	Poisons schedule included
8	Sponsor details updated in line with registration record and labels