Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Opticrom 2 % w/v Eye Drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Cromoglicate 2.0% w/v.

Excipients: Also includes benzalkonium chloride 0.01% w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

A clear, colourless to pale yellow, sterile, aqueous solution in a dropper bottle for ocular use.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief and treatment of allergic conjunctivitis and vernal keratoconjunctivitis (vernal or spring catarrh).

4.2 Posology and method of administration

One to two drops into each eye four times daily or as instructed by the physician.
Care should be taken to avoid contamination of the contents during use.

4.3 Contraindications

Use in patients sensitive to sodium cromoglicate or any of the ingredients.

4.4 Special warnings and precautions for use

As with all ophthalmic preparations containing benzalkonium chloride, patients should be advised not to wear soft contact lenses during treatment with Opticrom Eye Drops.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

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 only be used in pregnancy on the advice of a physician and where there is a clear need.

It is not known whether sodium cromoglicate is excreted in the breast milk, but on the basis of its physico-chemical properties this is considered unlikely. There is no evidence to suggest that 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 Opticrom may cause transient blurring of vision. Instillation of these eye drops may cause local irritation that could impact driving or operating machinery.

4.8 Undesirable effects

Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been recorded rarely.

Hypersensitivity reactions have been reported extremely rarely.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No action other than medical supervision should be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 of inflammation from mast cells.

Sodium cromoglicate has no intrinsic vasoconstrictor or antihistaminic activity.

5.2 Pharmacokinetic properties

Following topical ophthalmic administration of sodium cromoglicate to normal rabbit eyes, less than 0.07% of the dose is absorbed into the systemic circulation.

Similarly, in normal volunteers, analysis of urinary excretion of the drug indicates that only a very small proportion 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 ± 0.9ml $min^{-1}kg^{-1}$), so that any absorbed drug is rapidly cleared from the circulation and accumulation does not occur. Studies in the rabbit indicate that the drug does not accumulate in the eye.

Sodium cromoglicate is reversibly bound to plasma proteins (≈65%) and is not metabolised, being excreted unchanged in the bile and urine in approximately equal proportions.

5.3 Preclinical safety data

Animal studies have shown that sodium cromoglicate has a very low order of local or systemic toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Disodium edetate
Water for Injection

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 3 years.
Discard any remaining contents four weeks after first opening the bottle.

6.4 Special precautions for storage

Do not store above 30°C.
Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

Opticrom Eye Drops is presented as a clear colourless to pale yellow liquid in a 5ml, 10ml or 13.5 ml low density polyethylene dropper bottle, fitted with a low density polyethylene plug and a polypropylene cap.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Ltd. T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0540/116/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th December 1975

Date of last renewal: 15th February 2010

10 DATE OF REVISION OF THE TEXT

July 2017