# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Opticrom Allergy Single Dose 2% w/v eye drops, solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single dose container contains 2% w/v of sodium cromoglicate.
For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Eye drops, solution
A clear colourless or pale yellow liquid.
pH: 5.0 to 7.0
Osmolality: 280 to 340 mOsmol/kg

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the relief and treatment of seasonal and perennial allergic conjunctivitis.

### 4.2 Posology and method of administration

Posology
*Adults and children*
The recommended dose is one or two drops in each eye four times a day.
Opticrom Allergy single dose should be used regularly to ensure optimal control of symptoms. It is recommended that treatment is continued during the period of exposure to allergen.

Special population
*Older people*
No current evidence for alteration of the dose.

*Paediatric*
In children, caregiver supervision and/or assistance may be required.

Method of administration
For ocular use only.

It should be administered in the conjunctival sac of the affected eye.

To avoid contamination, the tip of the container should not touch the eye or any surface (see section 4.4).
As with most ophthalmic preparations, contact lenses should be removed before each application and may be inserted after 15 minutes.

In case of concomitant treatment with other eye drops, instillations should be 15 minutes apart.

### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

**4.4 Special warnings and precautions for use**

Opticrom Allergy single dose is sterile, preservative-free, and presented in a single dose container which should be used immediately after opening and any remaining contents discarded after use.

Patients wearing contact lenses: see section 4.2.

**4.5 Interaction with other medicinal products and other forms of interactions**

No interactions studies have been performed.

**4.6 Fertility, 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.

Breast-feeding
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.

Fertility
Animal studies did not show any effect on fertility. It is not known if sodium cromoglicate has an effect on human fertility.

**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. Patients are advised not to drive or operate machinery if affected, until their normal vision has been re-established.

**4.8 Undesirable effects**

Frequencies are based on the MedDRA frequency convention and defined as: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Eye Disorders
Not known: Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been reported.

Immune System Disorders
Not known: Local and system hypersensitivity reactions have been reported.

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: http://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

Pharmacotherapeutic group: Ophthalmologicals; 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

In normal volunteers, analysis of urinary excretion of the medicinal product 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 medicinal product has a high systemic clearance (plasma clearance 7.9 ± 0.9 ml min-1.kg-1), so that any absorbed medicinal product is rapidly cleared from the circulation and accumulation does not occur.

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

Non-clinical data are limited, however they do not reveal any special hazard for humans based on studies of repeated dose toxicity, genotoxicity, toxicity to reproduction and development.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium chloride
Purified water

### 6.2 Incompatibilities

Not applicable

**6.3 Shelf life**

Unopened: 3 years

After opening the sachet: 28 days

After opening the single dose container: the medicinal product must be used immediately.

**6.4 Special precautions for storage**

Before opening single dose container:
Store below 25°C. Keep the single dose containers in the aluminium sachet in order to protect from light.

After opening single dose container:
Discard any remaining contents after use.

**6.5 Nature and contents of container**

Low density polyethylene single dose containers containing 0.3 ml solution.
Packaging: 10 or 20 single dose containers packaged in an aluminium sachet.
Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7 MARKETING AUTHORISATION HOLDER**

Opella Healthcare France SAS T/A Sanofi
82 Avenue Raspail
94250 Gentilly
France

**8 MARKETING AUTHORISATION NUMBER**

PA23180/010/003

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 23rd January 2015
Date of last renewal: 9th November 2019

**10 DATE OF REVISION OF THE TEXT**

October 2021