Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Catacrom 2% w/v eye drops, solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium cromoglicate 2.0% w/v.

Each individual single-dose unit contains 6mg of sodium cromoglicate in 0.3ml of solution

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution (eye drops)

Clear, colourless solution in a single-dose container.

The eye drops are sterile and preservative free.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Catacrom 2% w/v eye drops are indicated for the relief and treatment of seasonal and perennial allergic conjunctivitis.

4.2 Posology and method of administration

Topical ophthalmic use.

Adults, children and the elderly: one or two drops into each eye four times per day, or as directed by the doctor.

4.3 Contraindications

Known hypersensitivity to sodium cromoglicate

4.4 Special warnings and precautions for use

Catacrom 2% w/v eye drops are sterile, preservative free and presented in a single-use container which should be discarded after use.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Catacrom 2% w/v eye drops should be used with caution in pregnancy, especially during the first trimester. Extensive experience with sodium cromoglicate suggests that there are no adverse effects on foetal development. Nevertheless, it should only be used in pregnancy where there is a clinical need.

It is not known whether sodium cromoglicate is excreted in breast milk; however, on the basis of its physicochemical properties, it is considered unlikely. There is no evidence 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, transient blurring of vision may occur on instillation. Do not drive or operate machinery until normal vision is restored.

4.8 Undesirable effects

On instillation, transient stinging or burning may occur. Rarely, other symptoms of local irritation 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: www.hpra.ie
e-mail: medsafety@hpra.ie

4.9 Overdose

Medical supervision only should be necessary.

If the solution is accidentally ingested, as sodium cromoglicate is only poorly absorbed, no action other than medical supervision should be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antiallergics; cromoglicic acid, ATC code: S01G X01

The solution exerts its effect locally in the eye. Sodium cromoglicate has been shown to inhibit the degranulation of sensitised mast cells occurring after exposure to specific antigens. Sodium cromoglicate inhibits release of histamine and various membrane derived mediators from mast cells.

Sodium cromoglicate has no intrinsic antihistaminic or vasoconstrictor activity.

5.2 Pharmacokinetic properties

Limited systemic absorption may be expected via ocular instillation.

In normal volunteers, analysis of drug excretion has shown that approximately 0.03% of sodium cromoglicate is absorbed following ocular administration.

5.3 Preclinical safety data

There are no findings of relevance to the prescriber other than those already mentioned elsewhere in the SPC

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

Sodium chloride

6.2 Incompatibilities

None known. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

Unopened: 3 years.

After opening the sachet: use contents within 28 days.

After opening the single-dose unit: use immediately after opening the single-dose unit. Discard any unused contents.

6.4 Special precautions for storage

Do not store above 25ºC. Store in the original package

6.5 Nature and contents of container

Catacrom 2% w/v eye drops are available in 0.3 ml low density polyethylene single-dose containers. The single dose containers are packed into laminate sachets, within a cardboard carton.

Pack sizes: 10, 12, 18, 20, 24, 30 or 90 single doses

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

For single use only. Discard immediately after first use. Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Rayner Pharmaceuticals Limited
10 Dominion Way
Worthing
West Sussex BN14 8AQ
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA2161/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th November 2009

Date of last Renewal: 6th August 2014

10 DATE OF REVISION OF THE TEXT

March 2018