1. NAME OF THE MEDICINAL PRODUCT

Sodium Cromoglicate 2% w/v Eye Drops, Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of eye drops contains

Active substance: 20 mg sodium cromoglicate (2.0% w/v), (one drop contains 0.7mg sodium cromoglicate).

Excipient: 0.1mg benzalkonium chloride

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye Drops, Solution

Clear colourless to pale yellow solution

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

Ocular use

Adults and Children over 6 years:
One or two drops to be administered into each eye four times daily.

Children under 6 years

There is no relevant indication for use of sodium cromoglicate in children. Sodium cromoglicate is contraindicated in children under 2 years of age.

Elderly

There is no evidence to suggest that dosage alteration is required for elderly patients.

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

Discard any remaining contents four weeks after opening the bottle.

Sodium cromoglicate eye drops contains benzalkonium chloride.

As with other ophthalmic solutions containing benzalkonium chloride, soft contact lenses should not be worn during the treatment period.

From the limited data available, there is no difference in the adverse event profile in children compared to adults. Generally, however, eyes in children show a stronger reaction for a given stimulus than the adult eye. Irritation may have an effect on treatment adherence in children.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised.

Patients should be monitored in case of prolonged use.

Sodium cromoglicate can be used prophylactically. Patients should seek advice before they discontinue use of the product.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Fertility:

It is not known whether sodium cromoglicate has any effect on fertility.

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 fetal development. It should be used in pregnancy only where there is a clear need.

Lactation:

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.

4.7 Effects on ability to drive and use machines

Sodium cromoglicate may interfere with the ability to drive and use machines.

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 vision returns to normal.

4.8 Undesirable effects

Eye disorders

Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been reported 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 Yellow Card Scheme at
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No action other than medical observation should be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: , ATC code: SO1GX01

The solution exerts its effect locally in the eye.

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

Sodium cromoglicate is poorly absorbed. When multiple doses of sodium cromoglicate ophthalmic solution are instilled into normal rabbit eyes, less than 0.07% of the administered dose of sodium cromoglicate is absorbed into the systemic circulation (presumably by way of the eye, nasal passages, buccal cavity and gastrointestinal tract). Trace amounts (less than 0.01%) of the sodium cromoglicate does penetrate into the aqueous humour and clearance from this chamber is virtually complete within 24 hours after treatment is stopped.

In normal volunteers, analysis of drug excretion indicates that approximately 0.03% of sodium cromoglicate is absorbed following administration to the eye.

Sodium cromoglicate is not metabolised.

5.3 Preclinical safety data

None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Benzalkonium chloride
Water for Injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

After first opening the bottle: 4 weeks
Discard any remaining solution four weeks after first opening.

6.4 Special precautions for storage

Before first opening the bottle: This medicinal product does not require any special storage conditions

After first opening the bottle: Do not store above 25°C.

6.5 Nature and contents of container

LDPE Blow Fill Seal (BFS) container with white polypropylene spiked screw cap having a tamper-proof base ring.

Pack sizes: 1x5ml and 1x10ml

Not all pack sizes may be marketed.

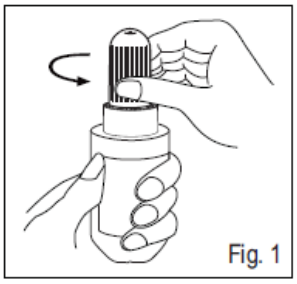
6.6 Special precautions for disposal and other handling

No special requirements

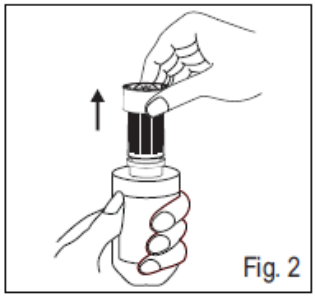
Opening the dropper container before first use

Note: Do not use the bottle if the tamper-proof base ring with cap is broken before you first use it.

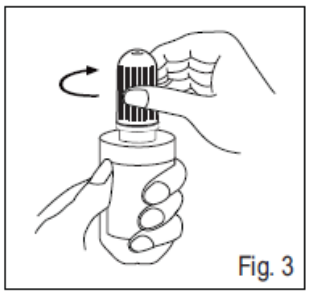
1. Turn the cap in counter clockwise direction. This will break the tamper-proof base ring (Fig.1).



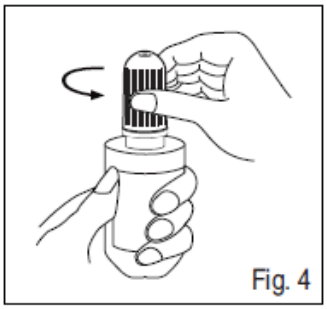
2. Remove the tamper-proof base ring by retaining the cap on the container (Fig.2).



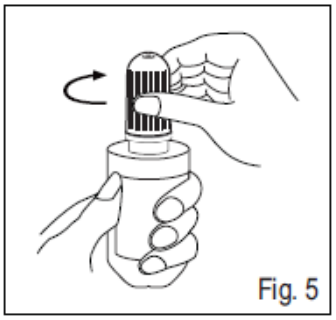
3. Tighten the cap on the nozzle so that the edge of the cap and the edge of bottle neck are totally aligned. Turning the screw cap clockwise will pierce the tip of the dropper container. (Fig.3).



4. To open the dropper container, remove the cap by turning it in the counter clockwise direction (Fig.4).



5. Tighten the cap on the container after every use (Fig.5).



7. MARKETING AUTHORISATION HOLDER

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5, Marryat Close
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8. MARKETING AUTHORISATION NUMBER(S)

PL 25298/0033

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/03/2012 / 21/02/2016

10. DATE OF REVISION OF THE TEXT

05/03/2022