Summary of Product Characteristics

1. Name of the medicinal product

Sodium Cromoglicate 2% w/v Eye Drops(ABCROM)

2. Qualitative and quantitative composition

Active substance: Sodium Cromoglicate 2% w/v

Excipient(s) with known effect:

Benzalkonium chloride

For the full list of excipients, see section 6.1For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Eye Drops, Solution

A clear colourless aqueous solution

4. Clinical particulars

4.1 Therapeutic indications

The prevention and treatment of acute, seasonal and perennial allergic conjunctivitis

4.2 Posology and method of administration

Adults and Children: One or two drops into each eye up to four times a day or as indicated by the doctor.

Elderly: There is no current evidence for alteration of the dose.

Route of administration:

Topical ophthalmic

4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients listed in section 6.1Hypersensitivity to the active substance, chloramphenicol or to any of the excipients listed in section 6.1

4.4 Special warnings and special precautions for use

This formulation of Sodium Cromoglicate Eye Drops contains benzalkonium chloride as a preservative which may be deposited in soft contact lenses. Hence, Sodium Cromoglicate Eye Drops should not be used while wearing these lenses. The lenses should be removed before instillation of the drops and not reinserted earlier than 15 minutes after use.

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.

Patients should also be instructed that ocular solutions, if handled improperly can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions. Patients should also be advised that if they develop any intercurrent ocular condition (e.g., trauma, ocular surgery or infection), they should immediately seek their physician's advice concerning the continued use of present multi-dose container. There have been reports of bacterial keratitis associated with the use of topical ophthalmic products

4.5 Interaction with other medicinal products and other forms of interaction

None known

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 foetal 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 based on its physicochemical properties this is considered unlikely Therefore caution should be exercised when the eye drops are administered to nursing mothers.

4.7 Effects on ability to drive and use machines

Transient blurring of vision may occur immediately after use and driving or using machinery should not occur until the vision is clear

4.8 Undesirable effects

Transient stinging and burning on instillation of the drops. Rarely, other symptoms of local irritation

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.

4.9 Overdose

Medical observation is recommended in cases of overdosage.

Sodium cromoglicate is poorly absorbed both from the eye and from the gastrointestinal tract.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Opthalmologicals; Other antiallergics,

ATC code : SO1GX01

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

5.3 Preclinical safety data

There is no pre-clinical safety data of relevance to the prescriber, therefore, none is presented in this section

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium chloride solution

Disodium edetate

Water for injection

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months (unopened).

28 days once opened

Discard four weeks of first opening

6.4 Special precautions for storage

Should be stored below 30^{o}C.Protect from heat. Do not freeze.

6.5 Nature and contents of container

Low density polyethylene dropper bottles and a white screw cap in pack sizes of 5mL and 10mL.

6.6 Special precautions for disposal and other handling

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

7. Marketing authorization holder

Abacus Parenteral Drugs Limited

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Email:apdl@abacuspharma.com

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8. Marketing authorization number(s)

04856/2789/NMR/2016

9. Date of first authorization/renewal of the authorization

25-12-2019

10. Date of revision of the text

June 2023