


ABACUS PARENTERAL DRUGS LTD.

SUMMARY OF PRODUCT CHARACTERISTICS

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|---|---|-----------------------------------|
| DEPARTMENT : QUALITY ASSURANCE | | DOCUMENT No. : SPC/QA/016 |
|  | TITLE : SODIUM CROMOGLICATE OPHTHALMIC SOLUTION 2.0% w/v, B.P (ABCROM) | REVISION STATUS : 00 |
| | | DATE OF ISSUE : 10/02/2016 |
| | | PAGE No. : 1 of 4 |

1. Name of the medicinal product

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

2. Qualitative and quantitative composition

Sodium Cromoglicate 2% w/v

3. Pharmaceutical form

Eye drops, solution.

A clear, colourless 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, Elderly & Children: One or two drops into each eye up to four times a day.

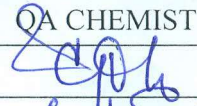


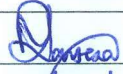
4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients


4.4 Special warnings and precautions for use

This formulation of Sodium Cromoglicate Eye Drops contains Benzalkonium chloride as a preservative. Benzalkonium chloride 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.

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

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| | | PAGE No. : 2 of 4 |

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. Pregnancy and lactation

There are no adequate and well-controlled studies of Sodium Cromoglicate eye drops in pregnant women. Therefore, use during pregnancy is not recommended unless the benefit outweighs the potential risk.

It is not known whether Sodium Cromoglicate is excreted in human milk. 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 stinging or blurring of vision may occur on instillation of the drops.

Do not drive or use machinery until normal vision is restored.

4.8 Undesirable effects

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

4.9 Overdose

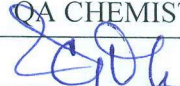

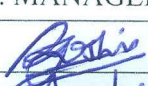
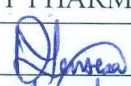
Medical observation is recommended in cases of overdosage.

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


5. Pharmacological properties

5.1 Pharmacodynamic properties

Sodium Cromoglicate inhibits the degranulation of sensitised mast cells which normally occurs after exposure to allergens and thereby prevents the release of allergic mediators such as histamine.

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| | | PAGE No. : 3 of 4 |

5.2 Pharmacokinetic properties

Sodium Cromoglicate is poorly absorbed from the eye (approximately 0.03% in healthy volunteers) due to its lipid insolubility. Orally, it is poorly absorbed from the gastrointestinal tract with a reported bioavailability of 1%. Systemically, sodium Cromoglicate is excreted unchanged in the bile and urine.

Trace amounts have been detected in the aqueous humour of rabbit eyes up to 24 hours after administration.

5.3 Preclinical safety data

Pre-clinical safety data does not add anything of further significance to the prescriber.

6. Pharmaceutical particulars**6.1 List of excipients**

- Disodium Edetate
- Benzalkonium Chloride Solution
- Water For Injections

6.2 Incompatibilities

Benzalkonium chloride may be deposited in and is known to discolour soft contact lenses. These lenses should therefore be removed before instillation of the eye drops and not reinserted earlier than 15 minutes after use.

6.3 Shelf life

Unopened: 18 months

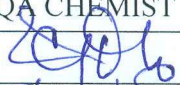



Discard the contents and bottle 28 days after opening the container for the first time.

6.4 Special precautions for storage

Store in a cool dry place below 30°C but do not freeze.

Keep out of the reach and sight of children.

Protect from light and always keep the container tightly closed

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