SUMMARY OF PRODUCT CHARACTERISTICS

Amoglat

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

1. Name of the medicinal product

Amoglat

2. Qualitative and quantitative composition

Sodium Cromoglicate Ph. Eur. ....2 % w/v

Aqueous vehicle ..... q.s.

Benzalkonium Chloride (As preservative)Ph. Eur. (0.01 % w/v)

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Eye Drops, solution.

Clear colourless solution free from visible particulate matter.

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 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 adequeate 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

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.

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, Sodium Chloride, Benzalkonium Chloride, Polysorbate 80, Water for Injection.

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: 2 years.

Opened: 28 days

Discard any remaining solution four weeks after first opening.

6.4 Special precautions for storage

Store in a dry place, below 30ºC & protect from light.

6.5 Nature and contents of container

Clear colourless solution free from visible particulate matter, is filled in 10 ml LDPE bottle with HIPS Spike cap comprising of HDPE screw cap over a LDPE with tamper evident LDPE dust-cover sealing the bottle cap. One such bottle is labelled with sticker label further packed in a carton along with insert.

6.6 Special precautions for disposal and other handling

No special instructions.

7 MARKETING AUTHORISATION HOLDER

Manufacturer:

FDC Ltd

B-8 MIDC Industrial Area, Waluj,

Aurangabad - 431136 Maharashtra,

India

Marketed by;

Bliss GVS Pharma Ltd.

102, Hyde Park, Saki-Vihar Road,

Andheri (East), Mumbai – 400072.

India

8. Marketing authorisation number(s)

H2024/CTD10066/21261

9. Date of first authorisation/renewal of the authorization

06 March 2024

10. Date of revision of the text

06 March 2024