1.5 Product Information

1.5.1 Prescribing Information (Summary of Product Characteristics)

"Prescription only medicine"

1. Name of the Medicinal Product:

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

2. Qualitative and Quantitative Composition:

a) Qualitative Composition

Product Name: AXACOMOCATE

Generic Name: Sodium Cromoglicate Eye Drops BP 2% w/v

Label Claim: Each mL contains:

Sodium Cromoglicate BP ..... %w/v
Benzalkonium Chloride Solution BP ..... %v/v
(As preservative)
Water for Injections BP ..... q.s

b) Quantitative Composition

Each mL of eye drops contains:
Active substances: 20 mg Sodium Cromoglicate (2.0% w/v)
Excipients with known effects: 0.0002 mL Benzalkonium Chloride Solution
For a full list of excipients, see section 6.1

3. Pharmaceutical Form

Eye Drops
Description: Clear Pale yellow solution.
Prescription Only Medicines

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

Topical ophthalmic administration
One or two drops in each eye four times a day or as indicated by the doctor.
Older people
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

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.

The patient should consult a doctor or pharmacist if symptoms do not start to improve within 48 hours. Sodium Cromoglicate Eye Drops BP 2% w/v eye drops should not be used continuously for more than 14 days except on the advice of a doctor or Pharmacist.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

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.

Fertility:

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

4.7 Effects on ability to drive and use machines

As with all eye drops, 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

<u>Eye disorders</u>

Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been reported rarely.

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 TMDA ADR reporting tool; website: http://imis.tmda.go.tz/arrt or search for TMDA Adverse Reactions Reporting Tool in the Google Play Store.

4.9 Overdose

Overdosage is very unlikely. In the event of accidental ingestion, symptomatic treatment is recommended.

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

Glycerin BP, Disodium Edetate BP, Polysorbate-80 BP, Benzalkonium Chloride Solution BP, Sodium Hydroxide BP, Water for Injections BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months from the date of manufacturing.
Use the solution within one month after opening vial.

6.4 Special precautions for storage

Store below 30ºC. Protect from light. Do not refrigerate or freeze.

6.5 Nature and contents of container

10 ml LDPE vial packed in a unit carton along with pack insert.

6.6 Special precautions for disposal and other handling

Tighten the cap on the nozzle as shown.
The spike in the cap will pierce the tip of the vial.
Dispense drops with gentle pressure.
Replace the cap after every use.
Not for Injection. For External Use Only
Use the solution within one month after opening the vial.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder

Axa Parenterals Limited
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8. Marketing Authorization Number(s)

9. Date of first authorization/renewal of the authorization

10. Date of revision of the text