Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Vezcrom (Cromolyn Sodium 2.0% w/v) Ophthalmic Solution USP

2. Qualitative and quantitative composition

Active substance: Cromolyn Sodium (2.0% w/v) 20mg/ml

Excipient with known effect: Benzalkonium chloride 0.01% w/v

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

5 ml Eye drop solution

A clear colourless to slight yellowish solution, free from any type of visible particles.

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 at regular intervals 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 6.1

4.4 Special warnings and precautions for use

This formulation of Cromolyn Sodium Eye Drops contains 0.1mg/ml (4.5 micrograms per dose) benzalkonium chloride as a preservative which may be deposited in soft contact lenses. Hence, Cromolyn Sodium 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 Cromolyn Sodium has any effect on fertility.

Pregnancy:

As with all medication, caution should be exercised especially during the first trimester of pregnancy. Cumulative experience with Cromolyn Sodium 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 Cromolyn Sodium 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.

Paediatric use:

Safety and effectiveness in children below the age of 4 years have not been established.

4.7 Effects on ability to drive and use machines.

Transient ocular 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

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions ND PQMPs to https://pv.pharmacyboardkenya.org

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

Frequencies are based on the MedDRA frequency convention and defined as: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Eye Disorders

Not known: Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been reported.

Immune System Disorders

Not known: Local and system hypersensitivity reactions have been reported.

4.9 Overdose

Medical observation is recommended in cases of overdosage.

Cromolyn Sodium 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 Cromolyn Sodium inhibits the degranulation of sensitised mast cells which occurs after exposure to specific antigens. Cromolyn Sodium acts by inhibiting the release of histamine and various membrane derived mediators from the mast cell.

Cromolyn Sodium 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. Cromolyn Sodium did not inhibit the enzymatic activity of released phospholipase A on its specific substrate.

Cromolyn Sodium has no intrinsic vasoconstrictor or antihistamine activity.

5.2 Pharmacokinetic properties

Cromolyn Sodium is poorly absorbed. When multiple doses of Cromolyn Sodium ophthalmic solution are instilled into normal rabbit eyes, less than 0.07% of the administered dose of Cromolyn Sodium 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 Cromolyn Sodium 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 Cromolyn Sodium is absorbed following administration to the eye.

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

Benzalkonium chloride
Sodium chloride
Sodium citrate
Edetate Disodium
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened: 24 months
After first opening of container: Discard solution 28 Days after opening the bottle.

6.4 Special precautions for storage:

Store below 30℃. Protect from direct sunlight.
Do not freeze.
To avoid contamination do not touch dropper tip to any surface.

6.5 Nature and contents of container

Cromolyn Sodium Ophthalmic Solution 2.0%w/v is supplied in a 5 ml white, opaque, plastic ophthalmic dropper bottle.

6.6 Special precautions for disposal and other handling:

No special instructions.

7. Marketing authorization holder and manufacturing site addresses

Marketing authorization holder:

Javia International Ltd.
c/o Arch Global Consult, The Junction Business Hub, Arsenal Branch Road, Celebasses, 20201
Country: Mauritius.

Manufacturing site address:
Indiana Ophthalmics Limited
135-137, Phase 2 G.I.D.C, Wadhwan-363035,
Surendranagar, Gujarat,
India.

8. Marketing authorization number
CTD10060

9. Date of first registration
05/07/2023

10. Date of revision of the text:
13/09/2023

11. Dosimetry:
Not Applicable

12. Instructions for Preparation of Radiopharmaceuticals:
Not Applicable