ICH CTD
MODULE 1.3

1.3 PRODUCT INFORMATION

1.3.1 Summary of product characteristics (SmPC)

Provided in the following pages.

Product Name: VITADIUM Eye Drops

[Sodium Chloride Eye Drops BP, 5% w/v (Hypertonic Solution)]

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

1.1 Product Name: VITADIUM Eye Drops

1.2 Strength: Provided in quality and quantitative composition.

1.3 Pharmaceutical Dosage Form: Eye Drops, Solution

2. Quality and Quantitative Composition:

2.1 Qualitative Declaration

2.2 Quantitative Declaration

Name of the Ingredients	Specification	Quantity/100 ml	Overage	Functions
Active Ingredient				
Sodium Chloride	BP	5.000 g	–	Hypertonicity agent
Excipients				
Mannitol	BP	4.500 g	–	Soothing agent
Boric Acid	BP	0.300 g	–	Buffering agent
Borax	BP	0.500 g	–	Buffering agent
Sodium Perborate	BP	0.010 g	–	Antimicrobial preservative
Sodium Hydroxide or Hydrochloric Acid	BP	qs to adjust pH at 6.0 – 8.0	–	pH Adjusting agent
Water for Injection	USP	qs to 100 ml	–	Solvent

3. Pharmaceutical Form:

Eye drops, solution. A clear and colorless solution, free from any sediment and foreign particles.

4. Clinical particulars

4.1 Therapeutic indications

VITADIUM is indicated for the temporary relief of corneal edema. It may also be used during eye exams.

4.2 Posology and method of administration

Instill 1 or 2 drops in the affected eye(s) every 3 or 4 hours, or as directed by the physician.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If condition worsens or persists for more than 72 hours or if you experience eye pain, changes in vision, continued redness or irritation of the eye consult a physician or ophthalmologist.

4.5 Interaction with other medicinal products and other forms of interaction

No significant interactions known or found for this OTC. Caution always advised with multiple medications.

4.6 Women of Child-Bearing Potential, Pregnancy, Breast-Feeding and Fertility

Pregnancy
May use during pregnancy; no human data available, though risk of fetal harm not expected based on expected limited systemic absorption.

Lactation
May use while breastfeeding; no human data available, though risk of infant harm and adverse effects on milk production not expected based on limited maternal systemic absorption.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation. Do not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

May cause transient mild stinging, burning or temporarily blurred vision.

4.9 Overdose

Overdose would not be expected to produce symptoms.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Hypertonicity agent.
ATC code: S01XA03

Mechanism of Action
Reduces corneal edema and associated symptoms by osmotic pressure control; draws excess fluid from cornea into tears.

5.2 Pharmacokinetic properties

Metabolism: none; CYP450: none
Excretion: urine; Half-life: unknown

5.3 Preclinical safety data

No adverse safety issues were detected during the development of this formulation. The active ingredients are well-established in clinical ophthalmology.

6. Pharmaceutical particulars

6.1 List of excipients

- Mannitol
- Boric Acid
- Borax
- Sodium Perborate
- Sodium Hydroxide or Hydrochloric Acid
- Water for Injections

6.2 Incompatibilities

None Known.

6.3 Shelf life

2 years from the date of manufacture..

6.4 Special precautions for storage

- Store below 30°C (86°F) and protect from light.
- Discard 30 days after opening.
- Keep out of the reach of children.

6.5 Nature and contents of container

LDPE dropper bottle sealed with LDPE tip and HDPE screw cap. Each box contains 1 labeled bottle containing 5 ml solution with a folded package insert.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Manufacturer

Aristopharma Ltd.
7, Purana Paltan Line, Dhaka – 1000, Bangladesh

8. Marketing Authorization Holder
VITACARE PHARMACY LIMITED, NO.33, OGBEOGOELIBUJORROADEAST, ASABA, DELTA, ASABA, , DELTA

9. Date of first authorization of the authorization

Date of inclusion: 19/12/2021