1.3 PRODUCT INFORMATION

1.3.1 Summary of product characteristics (SmPC)

Provided in the following pages.

ARISTOPHARMA LTD.

Gachha, Gazipur Sadar, Gazipur, Bangladesh

Product Name: Vita-Tears Eye Drops

(Carboxymethylcellulose Sodium & Glycerin Eye Drops, 0.5% / 0.9% w/v)

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

1.1 Product Name: Vita-Tears Eye Drops

1.2 Strength: Provided in quality and quantitative composition

1.3 Pharmaceutical Dosage Form: Eye Drops

2. Quality and Quantitative Composition:

2.1 Qualitative Declaration

2.2 Quantitative Declaration

Name of the Ingredient	Specifications	Quantity/ Per 100 ml	Overage	Justification
Active Ingredients				
Carboxymethylcellulose Sodium	USP	0.500 g	-	Lubricant
Glycerin	BP	0.900 g	-	Lubricant
Excipients				
Calcium Chloride Dihydrate	BP	0.010 g	-	Electrolyte
Potassium Chloride	BP	0.140 g	-	Electrolyte
Magnesium Chloride	BP	0.006 g	-	Electrolyte
Sodium Citrate Dihydrate	BP	0.100 g	-	Electrolyte
Borax (Sodium Tetraborate)	BP	0.200 g	-	Buffering Agent
Boric Acid	BP	0.700 g	-	Buffering Agent
Erythritol	USP NF	0.010 g	-	Osmo protector
Levocarnitine	USP	0.010 g	-	Osmo protector
Sodium Perborate	BP	0.010 g	-	Antimicrobial preservative
Sodium Hydroxide	BP	qs to adjust pH	-	pH adjusting agent
Hydrochloric Acid	BP	qs to adjust pH	-	pH adjusting agent
Water for Injections	USP	qs to 100.00 ml	-	Solvent

Product Name: Vita-Tears Eye Drops
(Carboxymethylcellulose Sodium & Glycerin Eye Drops, 0.5% / 0.9% w/v)

3. Pharmaceutical Form :

Pharmaceutical form: Eye Drops. A clear and colorless solution.

4. Clinical Particulars:

4.1 Therapeutic indications:

Indicated for the temporary relief of burning, irritation, and discomfort due to dryness of the eye or exposure to wind or sun.

4.2 Posology and method of administration:

Topical administration to the eye.
Instill 1 or 2 drops in the affected eye(s) as needed.

If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.

4.3 Contraindications:

Vita-Tears Eye Drops is contraindicated in patients with a known hypersensitivity to Carboxymethylcellulose Sodium or Glycerin, or any of the excipients listed in section 6.1.

4.4 Special warning and precautions for use:

For external use only. Keep out of reach of children. To avoid contamination, do not touch the tip of the container to any surface and avoid direct contact with the eye. If solution changes color or becomes cloudy, do not use. If experience eye pain, vision change, continued redness, eye irritation, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor. The eye drops may be used with contact lenses.

4.5 Undesirable effects:

Eye disorders:
Vision may be temporarily blurred when this product is first used. Also, minor burning/stinging/irritation may temporarily occur.

Reporting of suspected adverse reactions
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 the national reporting system.

4.6 Overdose and special antidotes:

Accidental overdose will present no hazard.

4.7 Fertility, pregnancy and lactation

Pregnancy and lactation
Due to the negligible systemic exposure and the lack of pharmacological activity Vita Tears Eye Drops can be used during pregnancy and lactation.

4.8 Effects on ability to drive and use machines

Vita Tears Eye Drops may cause transient blurring of vision which may impair the ability to drive or operate machines. The patient should wait until their vision has cleared before driving or using machinery.

5. Pharmacological Properties:

5.1 Pharmacodynamic Properties:

Pharmacotherapeutic group: Other ophthalmologicals
ATC code: S01XA20

Carboxymethylcellulose sodium has no pharmacological effect. Carboxymethylcellulose sodium has a high viscosity resulting in an increased retention time on the eye.

The excipients in Vita Tears Eye Drops were chosen to mimic the electrolyte constitution of tears.

5.2 Pharmacokinetic Properties:

Due to the high molecular weight (approx. 90,000 Daltons) Carboxymethylcellulose sodium is unlikely to penetrate the cornea.

5.3 Preclinical Safety Data:

There are no preclinical data considered relevant to clinical safety beyond data included in other sections of the SPC.

6. Pharmaceutical Particulars :

6.1 List of excipients:

- Calcium Chloride Dihydrate
- Potassium Chloride
- Magnesium Chloride
- Boric Acid
- Sodium Perborate
- Levocarnitine
- Erythritol

- Sodium Citrate
- Sodium Hydroxide
- Hydrochloric Acid
- Water for Injections

6.2 Incompatibilities:

None known.

6.3 Shelf life:

Two years from manufacture date.

6.4 Special precautions for storage:

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

6.5 Nature and contents of container:

Low Density Polyethylene (LDPE) white opaque dropper bottle with a LDPE white opaque dropper tip and High Density Polyethylene (HDPE) white opaque closure.
Pack size: 10 ml

7. Marketing Authorization Holder :

Name	:	Aristopharma Ltd.
Principal office	:	7 Purana Paltan Line, Dhaka-1000, Bangladesh
Site of manufacturer	:	Gachha, Gazipur Sadar, Gazipur, Bangladesh
e-mail	:	parvez@aristopharmabd.com

8. Marketing Authorization Numbers: 378-092-052

9. Date of first authorization / renewal of the authorization: 19/12/2021

10. Date of revision of the text: - To be given after approval of the product.