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## Sodium Hyaluronate, Polyethylene Glycol 400 & Propylene Glycol Eye Drops

### TRIAQUA™ EYE DROPS ट्रिक्वा

**1. Name of the Medicinal Product**  
TRIAQUA Eye Drops (10 ml)

**Composition**  
Sodium Hyaluronate Ph. Eur. 0.15% w/v  
Polyethylene Glycol 400 USP-NF 0.4% w/v  
Propylene Glycol IP 0.3% w/v  
Aqueous buffered vehicle q.s.

**2. Pharmaceutical Form**  
TRIAQUA Eye Drops are sterile solutions for topical ocular administration.

### 3. Clinical Particulars

#### 3.1 Therapeutic Indications

For the temporary relief of burning and irritation due to dryness of the eye.

#### 3.2 Posology and Method of Administration

**Posology**  
Pediatric Population The safety & efficacy of TRIAQUA Eye Drops in children has not been established.

#### Frequency of administration

As prescribed by the physician.

#### Method of Administration

TRIAQUA Eye Drops  
• Shake well before using.  
• Instill one or two drops in the eye(s) and blink.  
• May be used as needed throughout the day to relieve the symptoms of dry eye.

#### General Precautions

• For ocular use only.  
• If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.  
• It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of TRIAQUA Eye Drops.  
• Do not use if package has been opened or is damaged.

This product contains a level of Sodium Perborate and Boric acid that are safe when used according to label instructions.

#### 3.3 Contraindications

• People allergic to any ingredient in TRIAQUA Eye Drops should not use these products.

#### 3.4 Special Warnings and Precautions for Use

• 1. If irritation persists or increases, discontinue use and consult your physician.  
• 2. Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate the solution.  
• TRIAQUA Eye Drops is not indicated for use as a cleanser or disinfectant for contact lenses. Do not soak or disinfect your lenses in TRIAQUA Eye Drops.  
• Use the solution within one month after opening the container.  
• If the solution becomes cloudy or dark brown it should be discarded.

#### 3.5 Interaction with other Medicinal Products and Other Forms of Interaction

• No clinically relevant interactions have been described.

#### 3.6 Pregnancy and Lactation

##### Fertility

There are no adequate data regarding the impact of TRIAQUA Eye Drops on fertility. All of the ingredients in this product are pharmacologically inert compounds, generally classified as non-toxic and non-irritating.

##### Pregnancy

There are no adequate data for the use of TRIAQUA Eye Drops in pregnant women. All of the ingredients in this product are pharmacologically inert compounds, generally classified as non-toxic and non-irritating, therefore no effect during pregnancy is anticipated. This product can be used during pregnancy.

##### Breast-feeding

There are no adequate data regarding the impact of TRIAQUA Eye Drops on lactation. All of the ingredients in this product are pharmacologically inert compounds, generally classified as non-toxic and non-irritating, therefore no effect during lactation is anticipated. This product can be used during breastfeeding.

#### 3.7 Effects on Ability to Drive and Use Machines

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines.  
If blurred vision occurs at application, the patient must wait until the vision clears before driving or using machinery.

#### 3.8 Undesirable Effects

The common side-effects of TRIAQUA Eye Drops are

application site reactions such as burning/stinging sensation or redness in the eye, itching, irritation, blurred vision. These side-effects are usually mild and temporary. Consult your doctor if these side-effects persists.

Sodium Hyaluronate may cause side effects like headache, pain at the injection site, skin irritation and discolouration, eye pain and discomfort etc.

#### 3.9 Overdose

Due to the characteristics of this preparation, no toxic effect is to be expected with an ocular overdose of this product, nor in the event of an accidental ingestion of the contents of one bottle.

### 4. Pharmacological Properties

#### 4.1 Pharmacodynamic Properties

Pharmacodynamic studies with TRIAQUA Eye Drops were not performed.

#### 4.2 Pharmacokinetic Properties

Pharmacokinetic studies with TRIAQUA Eye Drops were not performed.

#### 4.3 Preclinical Safety Data

Non-clinical data reveal no special hazard for humans based on conventional studies or risk assessment of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

### 5. Pharmaceutical Particulars

#### 5.1 List of Ingredients

Ingredients	
Polyethylene Glycol 400 USP-NF	
Propylene Glycol	IP
Sodium Hyaluronate	Ph. Eur.
Magnesium Chloride	IP
Potassium Chloride	IP
Sodium Chloride	IP
Sodium Hydroxide	IP
Hydrochloric Acid	IP
Boric Acid	IP
Calcium Chloride	IP
Sodium Perborate	BP

#### 5.2 Incompatibilities

Not applicable.

#### 5.3 Storage:

Store in a dry place at a temperature not exceeding 30°C.

Protect from light. Do not freeze.

#### 5.4 Nature and Contents of Container

TRIAQUA Eye Drops is available in 10 ml vial packed in a

carton along with a Package insert.

#### 5.5 Instructions for Use, Handling and Disposal

- Close the cap tightly after every usage.
- If swallowed, get medical help.
- To avoid contamination, never touch the tip of the dropper vial to any surface.
- Use before the expiration date marked on the product.
- If the solution becomes discolored or blurry, the product should not be used
- The vial is ready for use when the cap is opened.
- Keep out of the reach of children.
- Keep container tightly closed when not in use.
- Can be used for up to one month after opening.
- Discard any remaining solution one month after First opening.

Marketed by:



**LUMIN LABS LLP**  
D2-304, Siyona Pethkar, Punawale,  
Mumbai - Bangalore Highway,  
Pune-411033

TM - Applied Trade Mark

Manufactured in India by :  
Appasamy Ocular Devices (P) Ltd.  
Plot No. 74-D, Katha, Baddi,  
Distt. Solan (H.P.) - 173205

180.00 mm

148.00 mm

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