



# GenTeal Tears (Moderate)

Dosage form: solution/ drops

Ingredients: Dextran 70 1mg in 1mL, Glycerin 2mg in 1mL, Hypromelloses 3mg in 1mL

Labeler: Alcon Laboratories, Inc.

NDC Code: 0065-0426

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

## Drug Facts

| <b>Active ingredients</b> | <b>Purpose</b> |
|---------------------------|----------------|
| Dextran 70 0.1%           | Lubricant      |
| Glycerin 0.2%             | Lubricant      |
| Hypromellose 0.3%         | Lubricant      |

## Uses

- temporary relief of burning and irritation due to dryness of the eye
- as a protectant against further irritation
- temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun

## Warnings

**For external use only**

### Do not use

- if this solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product

### When using this product

- do not touch tip of container to any surface to avoid contamination
- replace cap after each use

**Stop use and ask a doctor if you experience any of the following:**

- you feel eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists for more than 72 hours

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

- put 1 or 2 drops in the affected eye(s) as needed

## Other Information

- store between 15°- 25°C (59°- 77°F).

### ***Inactive Ingredients***

Boric acid, calcium chloride, glycine, hydrochloric acid and/or sodium hydroxide (to adjust pH), magnesium chloride, POLYQUAD® (polyquaternium-1) 0.001% preservative, polysorbate 80, potassium chloride, purified water, sodium chloride, zinc chloride.

### ***Questions?***

In the U.S. call 1-800-757-9195  
(Mon-Fri 9AM-5PM CST)  
alcon.medinfo@alcon.com

### **PRINCIPAL DISPLAY PANEL**

NDC 0065-0426-36

### **Moderate DRY EYE SYMPTOM RELIEF**

GenTeal\* Tears

LUBRICANT EYE DROPS

LIQUID DROPS

Fast Soothing Relief

### ***PREVIOUSLY TEARS NATURALE\* FORTE***

STERILE 15 mL (0.5 FL OZ)

Alcon®

GenTeal\* Tears Moderate Lubricant Eye Drops contains Triple Demulcent Technology. This combination of ingredients works together to retain moisture on the eye and slow evaporation of the tear film.

GenTeal\* Tears Moderate Lubricant Eye Drops is designed to more closely mimic your natural tears. The formulation of GenTeal\* Tears Moderate Lubricant Eye Drops protects against the recurrence of dry eye symptoms.

ACTUAL SIZE

**TAMPER EVIDENT:** For your protection, this bottle has an imprinted seal around the neck. Do not use if seal is damaged or missing at time of purchase.

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**ALCON LABORATORIES, INC.**  
Fort Worth, Texas 76134 USA  
a Novartis company

Country of Origin: USA

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LOT:

EXP.:



NDC 0065-0426-36

Moderate DRY EYE SYMPTOM RELIEF

GenTeal\* Tears

LUBRICANT EYE DROPS

LIQUID DROPS

Fast Soothing Relief

STERILE 15 mL (0.5 FL OZ)

**STERILE – FOR TOPICAL EYE USE ONLY**

**Uses:** For the temporary relief of burning and irritation due to dryness of the eye and for use as a protectant against further irritation. For the temporary relief of discomfort due to minor irritation of the eye or to exposure to wind or sun.

**Directions:** put 1 or 2 drops in the affected eye(s) as needed.

**Warnings:** If solution changes color or becomes cloudy, do not use. To avoid contamination, do not touch tip of container to any surface. Replace cap after using. Keep this and all drugs out of the reach of children. See carton for complete **Warnings**.

**INGREDIENTS:** Each mL contains: **Active:** Dextran 70 0.1%, Glycerin 0.2% and Hypromellose 0.3%. **Preservative:** POLYQUAD\* (polyquaternium-1) 0.001%. **Inactives:** Boric acid, calcium chloride, glycine, hydrochloric acid and/or sodium hydroxide (to adjust pH), magnesium chloride, polysorbate 80, potassium chloride, purified water, sodium chloride, zinc chloride.

**TAMPER EVIDENT:** For your protection, this bottle has an imprinted seal around the neck. Do not use if seal is damaged or missing at time of purchase. Store at room temperature.

**Alcon**<sup>®</sup>

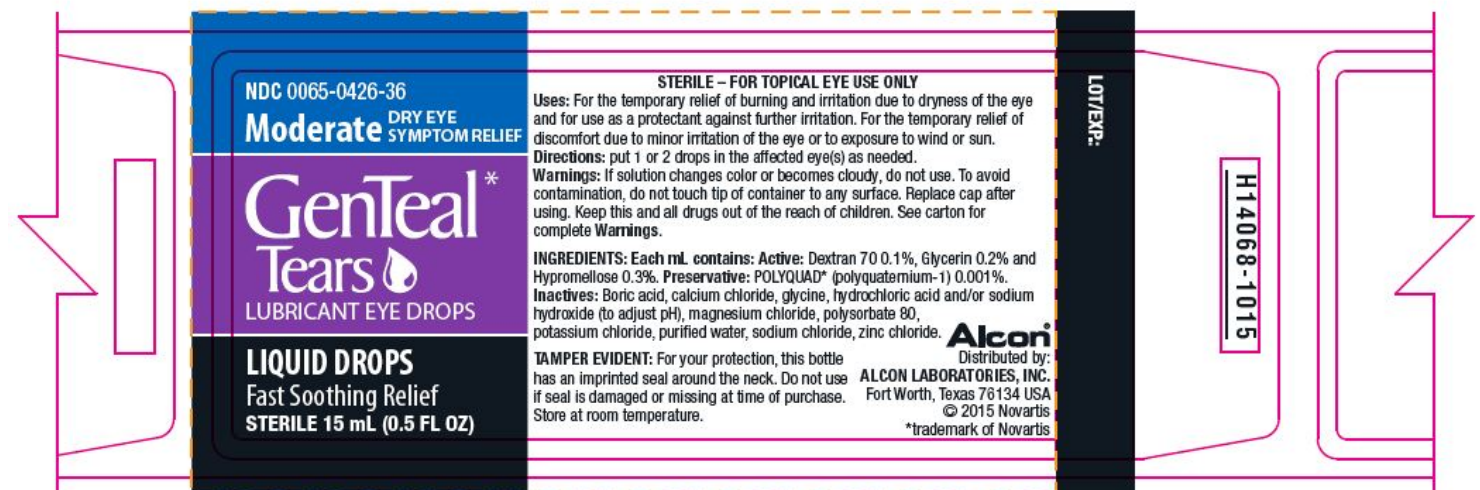
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STERILE 15 mL (0.5 FL OZ)

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LOT/EXP.:

H14068-1015



**GENTEAL TEARS (MODERATE)**

## Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:0065-0426 |
| Route of Administration | OPHTHALMIC     | DEA Schedule       |               |

## Active Ingredient/Active Moiety

| Ingredient Name               | Basis of Strength | Strength     |
|-------------------------------|-------------------|--------------|
| Dextran 70 (Dextran 70)       | Dextran 70        | 1 mg in 1 mL |
| Glycerin (Glycerin)           | Glycerin          | 2 mg in 1 mL |
| Hypromelloses (Hypromelloses) | Hypromelloses     | 3 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name      | Strength |
|----------------------|----------|
| Boric Acid           |          |
| Calcium Chloride     |          |
| Glycine              |          |
| Hydrochloric Acid    |          |
| Sodium Hydroxide     |          |
| Magnesium Chloride   |          |
| Polidronium Chloride |          |
| Polysorbate 80       |          |
| Potassium Chloride   |          |
| Water                |          |
| Sodium Chloride      |          |
| Zinc Chloride        |          |

## Packaging

| # | Item Code        | Package Description           |
|---|------------------|-------------------------------|
| 1 | NDC:0065-0426-36 | 1 BOTTLE, DROPPER in 1 CARTON |
| 1 |                  | 15 mL in 1 BOTTLE, DROPPER    |
| 2 | NDC:0065-0426-37 | 2 BOTTLE, DROPPER in 1 CARTON |
| 2 |                  | 15 mL in 1 BOTTLE, DROPPER    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part349                                  | 03/01/2016           |                    |

**Labeler** - Alcon Laboratories, Inc. (008018525)

## Establishment

| Name               | Address | ID/FEI    | Operations             |
|--------------------|---------|-----------|------------------------|
| Alcon Research Ltd |         | 007672236 | manufacture(0065-0426) |

Revised: 01/2016  
Alcon Laboratories, Inc.

Disclaimer: Every effort has been made to ensure that the information provided here is accurate, up-to-date and complete, but no guarantee is made to that effect. Drug information contained herein may be time sensitive. This information has been compiled for use by healthcare practitioners and consumers in the United States. The absence of a warning for a given drug or combination thereof in no way should be construed to indicate that the drug or combination is safe, effective or appropriate for any given patient. If you have questions about the substances you are taking, check with your doctor, nurse or pharmacist.