

GENTEAL TEARS MODERATE PRESERVATIVE FREE- dextran 70, hypromellose 2910 solution/ drops

Alcon Laboratories, Inc.

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

| Active Ingredients | Purpose |
|---------------------------|----------------|
| Dextran 70 0.1% | Lubricant |
| Hypromellose 2910 0.3% | Lubricant |

Uses

- 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

- to avoid contamination, do not touch tip of container to any surface
- do not reuse
- once opened, discard

Stop use and ask a doctor if

you experience any of the following:

- 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 at room temperature 15° – 25° C (59° – 77° F)

Inactive ingredients

potassium chloride, purified water, sodium borate, sodium chloride. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions?

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

PRINCIPAL DISPLAY PANEL

GenTeal[®] Tears
LUBRICANT EYE DROPS

PRESERVATIVE FREE
Moderate DRY EYE SYMPTOM RELIEF

PRESERVATIVE FREE
Moderate DRY EYE SYMPTOM RELIEF

GenTeal[®] Tears
LUBRICANT EYE DROPS
LIQUID DROPS

Fast, Soothing Relief
Preservative Free Formula

**Previously
TEARS
NATUREL[®]
FREE
LUBRICANT
EYE DROPS**

STERILE 36 Single-Use Vials 0.9mL (0.03 FL OZ) Each

Alcon

GenTeal[®] Tears Lubricant Eye Drops Preservative Free provide lasting relief for moderate dry eye with the convenience of a vial.

TAMPER EVIDENT:
Do not use if vial is damaged or opened.

Distributed by:
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Fort Worth, Texas 76134
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| Use | |
| ■ 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 | |
| ■ to avoid contamination, do not touch tip of container to any surface | |
| ■ do not reuse | |
| ■ once opened, discard | |
| Stop use and ask a doctor if you experience any of the following: | |
| ■ 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 at room temperature 15°-25° C (59°-77° F) | |
| Inactive ingredients | |
| potassium chloride, purified water, sodium borate, sodium chloride. May contain hydrochloric acid and/or sodium hydroxide to adjust pH. | |
| Questions? | |
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PRESERVATIVE FREE

GenTeal[®] Tears

LUBRICANT EYE DROPS

(Dextran 70 0.1% and
Hypromellose 2910 0.3%)



Directions:

Make sure container is intact
before use.

To open, completely **TWIST** off tab
Do **NOT** pull off



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



Throw away container.
Do not reuse

PRESERVATIVE FREE

Moderate DRY EYE SYMPTOM RELIEF

GenTeal[®] Tears
LUBRICANT EYE DROPS

LIQUID DROPS

Fast, Soothing Relief
Preservative Free Formula

Previously **TEARS NATURALE[®] FREE LUBRICANT EYE DROPS**

STERILE 36 Single-Use Vials 0.9 mL (0.03 FL OZ) Each

Alcon[®]

GENTEAL TEARS MODERATE PRESERVATIVE FREE

dextran 70, hypromellose 2910 solution/ drops

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0065-8063 |
| Route of Administration | OPHTHALMIC | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|--------------|
| Hypromellose 2910 (4000 Mpa.s) (UNII: RN3152OP35) (Hypromellose 2910 (4000 Mpa.s) - UNII:RN3152OP35) | Hypromellose 2910 (4000 Mpa.s) | 3 mg in 1 mL |
| Dextran 70 (UNII: 7SA290YK68) (Dextran 70 - UNII:7SA290YK68) | Dextran 70 | 1 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Potassium Chloride (UNII: 660YQ98110) | |
| Water (UNII: 059QF0K00R) | |
| Sodium Borate (UNII: 91MBZ8H3QO) | |
| Hydrochloric Acid (UNII: QTT17582CB) | |
| Sodium Hydroxide (UNII: 55X04QC32I) | |
| Sodium Chloride (UNII: 451W47IQ8X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0065-8063-01 | 36 in 1 CARTON | 12/22/2017 | |
| 1 | | .9 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part349 | 12/22/2017 | |

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|------------------------|
| Catalent Pharma Solutions, LLC | | 043911403 | manufacture(0065-8063) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| Kaysersberg Pharmaceuticals | | 267486052 | manufacture(0065-8063) |

Revised: 3/2018

Alcon Laboratories, Inc.