

GENTEAL MILD TO MODERATE- hypromellose liquid
Novartis Pharmaceutical Corporation

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

OTC - ACTIVE INGREDIENT SECTION

Hypromellose (0.3%)

OTC - PURPOSE SECTION

Lubricant

INDICATIONS & USAGE SECTION

- Relieves dryness of the eye.
- Temporarily relieves discomfort due to minor irritations of the eye or from exposure to wind and sun.
- As a protectant against further irritation.

WARNINGS SECTION

For external use only.

OTC - DO NOT USE SECTION

Do not use

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

OTC - WHEN USING SECTION

When using this product do not touch tip of container to any surface. Replace cap after using.

OTC - STOP USE SECTION

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

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION SECTION

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

OTHER SAFETY INFORMATION

Store between 15°- 25°C (59°- 77°F).

INACTIVE INGREDIENT SECTION

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

OTC - QUESTIONS SECTION

In the U.S., call toll-free **1-866-393-6336**;

MedInfo@AlconLabs.com

Serious side effects associated with use of this product may be reported to this telephone number.

www.gentel.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 0078-0518-2

Mild to Moderate

Dry Eye Relief

GenTeal®

LUBRICANT EYE DROPS

LIQUID DROPS

Fast, Soothing Relief

Alcon®

STERILE 15 mL (0.5 fl oz)

NDC 0078-0518-24

**Mild to Moderate
Dry Eye Relief**

GenTeal[®]
LUBRICANT EYE DROPS

GenTeal[®] Mild to Moderate Drops delivers fast, soothing relief of your dry eye symptoms.

25314101

TAMPER EVIDENT.
For your protection, this bottle has a tamper evident cap. Do not use if cap and neck ring are not intact at time of purchase.

Made in Switzerland for:
Alcon Laboratories, Inc.,
a Novartis company
6201 South Freeway
Fort Worth, TX 76134 USA

Alcon[®]

STERILE 15 mL (0.5 fl oz)

Drug Facts

| Active ingredient | Purpose |
|---------------------|-----------|
| Hypromellose (0.3%) | Lubricant |

Uses

- Relieves dryness of the eye.
- Temporarily relieves discomfort due to minor irritations of the eye or from exposure to wind and sun.
- As a protectant against further irritation.

Warnings

For external use only.
Do not use

- if 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. Replace cap after using.

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 between 15°- 25°C (59°- 77°F).

Inactive ingredients

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

Questions? In the U.S., call toll-free **1-866-393-6336**; MedInfo@AlconLabs.com Serious side effects associated with use of this product may be reported to this telephone number. www.gentel.com

GenTeal[®]
LUBRICANT EYE DROPS

GenTeal[®] Products:

- Mild Liquid Drops
- Mild to Moderate Liquid Drops
- Moderate to Severe Liquid Gel Drops
- Severe Gel
- Night-time PM Ointment

U.S. Patent Nos.
5,607,698; 5,683,993; 5,858,996

Alcon[®]
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GENTEAL MILD TO MODERATE

hypromellose liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0078-0518 |
| 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) | 0.003 L in 1 L |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Boric Acid (UNII: R57ZHV85D4) | |
| Phosphonic Acid (UNII: 35V6A8JW8E) | |
| Potassium Chloride (UNII: 660YQ98110) | |
| Water (UNII: 059QF0KO0R) | |
| Sodium Chloride (UNII: 451W47IQ8X) | |
| Sodium Perborate (UNII: Y52BK1W96C) | |
| Hydrochloric Acid (UNII: QTT17582CB) | |

Sodium Hydroxide (UNI: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------|----------------------|--------------------|
| 1 | NDC:0078-0518-24 | .015 L in 1 BOTTLE, DROPPER | | |
| 2 | NDC:0078-0518-16 | .025 L in 1 BOTTLE, DROPPER | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part349 | 09/14/2009 | |

Labeler - Novartis Pharmaceutical Corporation (002147023)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|------------------------|
| EXCELVISION AG | | 482198285 | MANUFACTURE(0078-0518) |

Revised: 9/2012

Novartis Pharmaceutical Corporation