**GENTEAL MILD- 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.*

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**Drug Facts**

## OTC - ACTIVE INGREDIENT SECTION

Hypromellose (0.2%)

## 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 AND ASK A DOCTOR

**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

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, calcium chloride dihydrate, 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.genteal.com

## PRINCIPAL DISPLAY PANEL

NDC 0078-0517-24

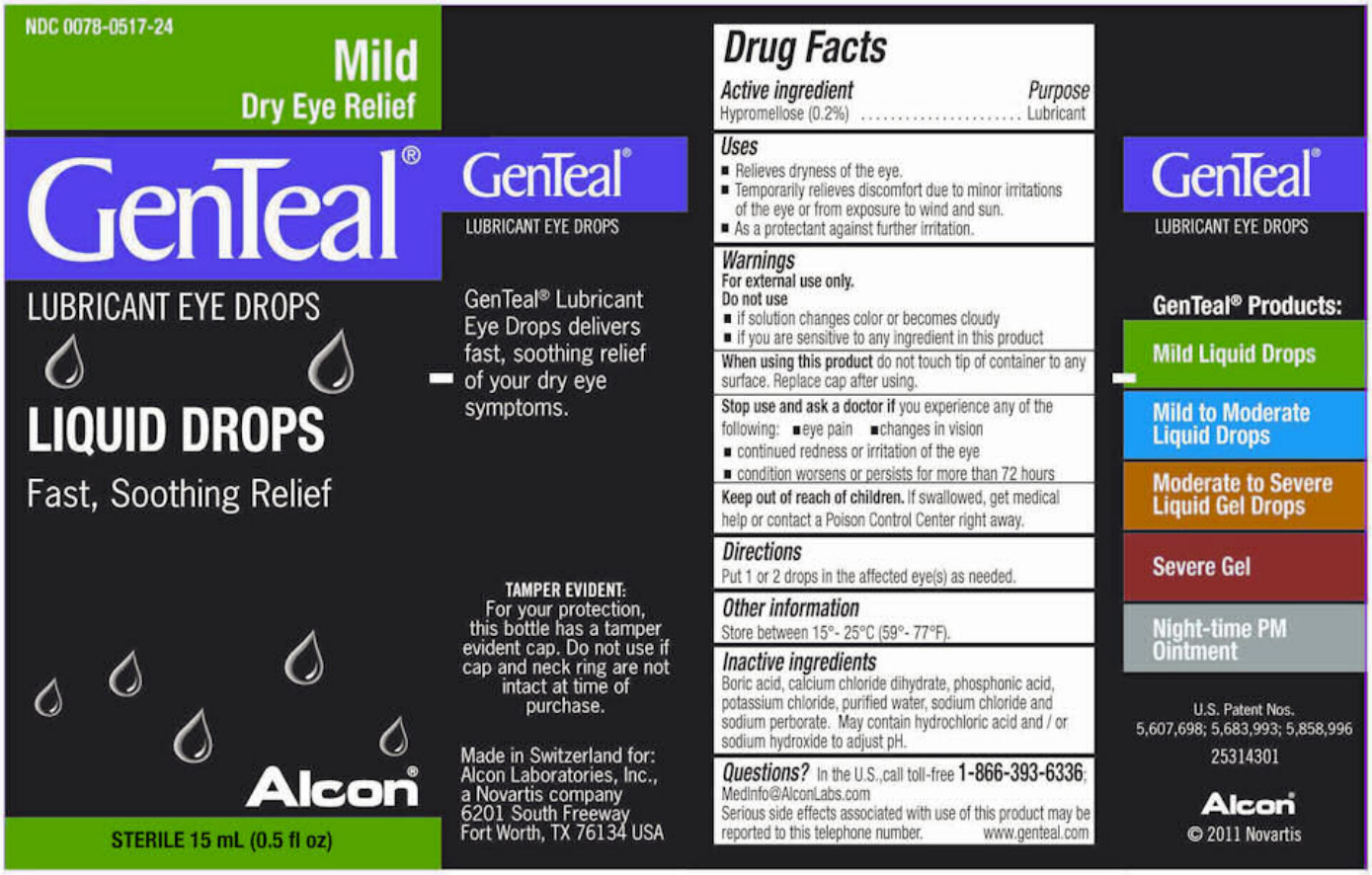
**Mild**
Dry Eye Relief

**GenTeal®**
LUBRICANT EYE DROPS

**LIQUID DROPS**
Fast, Soothing Relief

**Alcon®**

STERILE 15 mL (0.5 fl oz)




# GENTEAL MILD

hypromellose liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0078-0517 |
| **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) | 200 mg in 1 L |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **Boric Acid** (UNII: R57ZHV85D4) | |
| **Calcium Chloride** (UNII: M4I0D6VV5M) | |
| **Phosphonic Acid** (UNII: 35V6A8JW8E) | |
| **Potassium Chloride** (UNII: 660YQ98I10) | |
| **Water** (UNII: 059QF0KO0R) | |
| **Sodium Chloride** (UNII: 451W47IQ8X) | |
| **Sodium Perborate** (UNII: Y52BK1W96C) | |
| **Hydrochloric Acid** (UNII: QTT17582CB) | |

| | |
|---|---|
| **Sodium Hydroxide** (UNII: 55X04QC32I) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0078-0517-24 | .015 L in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 09/14/2009 | 10/31/2017 |
| **2** | NDC:0078-0517-16 | .025 L in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 09/14/2009 | |

## 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(0078-0517) |

Revised: 7/2019 Novartis Pharmaceutical Corporation