

**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)

NDC 0078-0517-24

**Mild  
Dry Eye Relief**

**GenTeal®**

**GenTeal®**  
LUBRICANT EYE DROPS

LUBRICANT EYE DROPS

**LIQUID DROPS**

Fast, Soothing Relief

GenTeal® Lubricant Eye Drops delivers fast, soothing relief of your dry eye symptoms.

**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** Hypromellose (0.2%) ..... **Purpose** 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, 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.

**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.genteal.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  
 25314301

**Alcon®**  
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**GENTEAL MILD**

hypromellose liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0078-0517
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Hypromellose 2910 (4000 Mpa.s)</b> (UNII: RN3152OP35) (Hypromellose 2910 (4000 Mpa.s) - UNII:RN3152OP35)	Hypromellose 2910 (4000 Mpa.s)	200 mg in 1 L

**Inactive Ingredients**

Ingredient Name	Strength
<b>Boric Acid</b> (UNII: R57ZHV85D4)	
<b>Calcium Chloride</b> (UNII: M410D6VV5M)	
<b>Phosphonic Acid</b> (UNII: 35V6A8JW8E)	
<b>Potassium Chloride</b> (UNII: 660YQ98I10)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	
<b>Sodium Perborate</b> (UNII: Y52BK1W96C)	
<b>Hydrochloric Acid</b> (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