## GENTEAL MILD- hypromellose 2910 (4000 mpa.s) 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

 $GenTeal^{\mathbb{R}}$ 

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 LABEL	Item Code (Source)	NDC:0078-0517	
Route of Administration	OPHTHALMIC	DEA Schedule		

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength Hypromellose 2910 (4000 Mpa.s) (Hypromellose 2910 (4000 Mpa.s)) Hypromellose 2910 (4000 Mpa.s) 0.002 L in 1 L

Inactive Ingredients		
Ingredient Name	Strength	
Boric Acid		
Calcium Chloride		
Phosphonic Acid		
Potassium Chloride		
Water		
Sodium Chloride		
Sodium Perborate		
Hydrochloric Acid		

#### Sodium Hydroxide

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0078-0517-24	.015 L in 1 BOTTLE, DROPPER		
2	NDC:0078-0517-16	.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(0078-0517)	

Revised: 9/2012 Novartis Pharmaceutical Corporation