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.

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)	0.002 L 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		
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