

GENTEAL TEARS (MILD) - dextran 70 and hypromellose 2910 solution/ drops
Alcon Laboratories, Inc.

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

<i>Active Ingredients</i>	<i>Purpose</i>
Dextran 70 0.1%	Lubricant
Hypromellose 2910 0.3%	Lubricant

Uses

- temporary relief of burning and irritation due to dryness of the eye
- temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or 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

- to avoid contamination, 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 at room temperature

Inactive ingredients:

POLYQUAD* (polyquaternium-1) 0.001% preservative, potassium chloride, purified water, sodium borate and sodium chloride. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions?

In the U.S. call 1-800-757-9195
(Mon-Fri 9AM-5PM CST)
alcon.medinfo@alcon.com

PRINCIPAL DISPLAY PANEL

NDC 0065-0418-81

Mild DRY EYE SYMPTOM RELIEF

GenTeal* Tears

LUBRICANT EYE DROPS

LIQUID DROPS

Soothing Relief

PREVIOUSLY TEARS NATURALE* II

STERILE 15 mL (0.5 FL OZ)

Alcon®

TAMPER EVIDENT:

For your protection, this bottle has an imprinted seal around the neck. Do not use if seal is damaged or missing at time of purchase.

GenTeal* Tears Mild Lubricant Eye Drops contains POLYQUAD* preservative, a safe and comfortable preservative, gentle enough for even sensitive eyes.

Distributed by:

ALCON LABORATORIES, INC.

Fort Worth, Texas 76134 USA

a Novartis company

Country of Origin: USA

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ACTUAL SIZE

9013370-0716

LOT:

EXP.:

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Drug Facts (continued)

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LIQUID DROPS

Soothing Relief

STERILE 15 mL (0.5 FL OZ)

STERILE – FOR TOPICAL EYE USE ONLY

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Alcon®

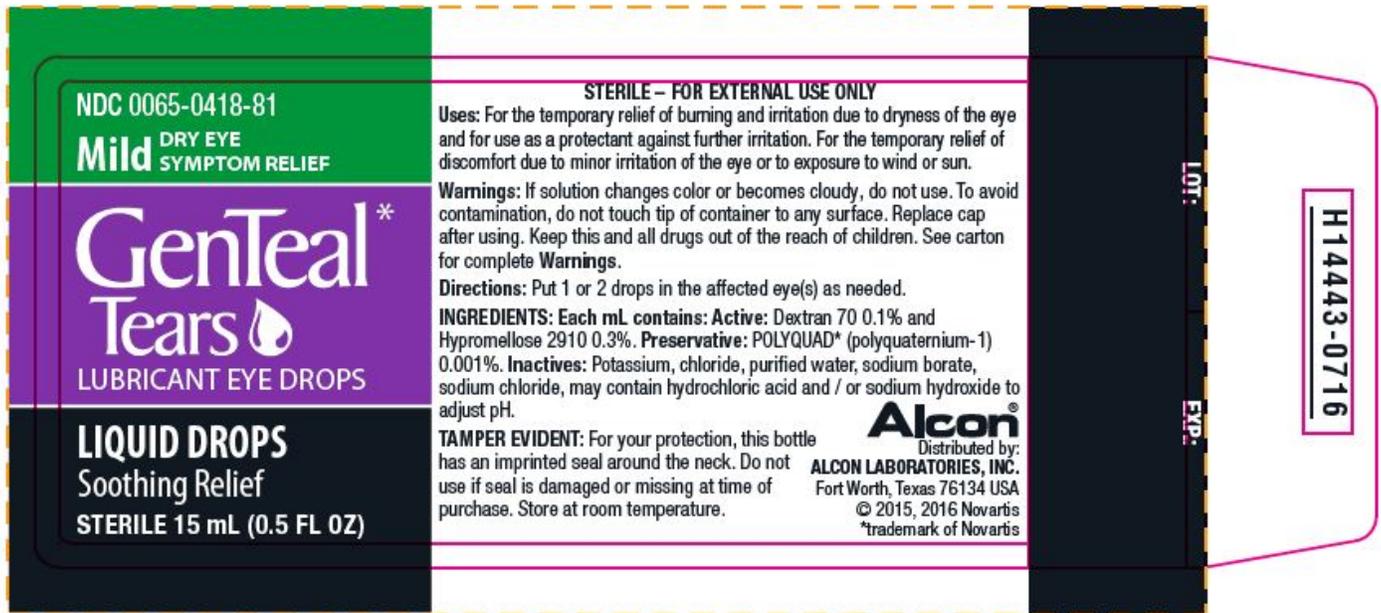
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LOT/EXP.:

H14443-0716



GENTEAL TEARS (MILD)

dextran 70 and hypromellose 2910 solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0065-0418
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextran 70 (UNII: 7SA290YK68) (Dextran 70 - UNII:7SA290YK68)	Dextran 70	1 mg in 1 mL
Hypromellose 2910 (4000 Mpa.s) (UNII: RN3152OP35) (Hypromellose 2910 (4000 Mpa.s) - UNII:RN3152OP35)	Hypromellose 2910 (4000 Mpa.s)	3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Polidronium Chloride (UNII: 6716Z5YR3G)	
Potassium Chloride (UNII: 660YQ98110)	
Water (UNII: 059QF0K00R)	
Sodium Borate (UNII: 91MBZ8H3QO)	
Sodium Chloride (UNII: 451W47IQ8X)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0418-81	1 in 1 CARTON	03/01/2016	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:0065-0418-80	2 in 1 CARTON	03/01/2016	
2		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	03/01/2016	

Labeler - Alcon Laboratories, Inc. (008018525)**Establishment**

Name	Address	ID/FEI	Business Operations
Alcon Research LLC		007672236	manufacture(0065-0418)

Revised: 12/2019

Alcon Laboratories, Inc.