

GENTEAL TEARS (MODERATE) - dextran 70, glycerin, hypromellose 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

Active ingredients	Purpose
Dextran 70 0.1%	Lubricant
Glycerin 0.2%	Lubricant
Hypromellose 0.3%	Lubricant

Uses

- temporary relief of burning and irritation due to dryness of the eye
- as a protectant against further irritation
- temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun

Warnings

For external use only

Do not use

- if this 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 to avoid contamination
- replace cap after each use

Stop use and ask a doctor if you experience any of the following:

- you feel 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:

boric acid, calcium chloride, glycine, hydrochloric acid and/or sodium hydroxide (to adjust pH), magnesium chloride, POLYQUAD* (polyquaternium-1) 0.001% preservative, polysorbate 80, potassium chloride, purified water, sodium chloride, zinc chloride.

Questions?

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

PRINCIPAL DISPLAY PANEL

NDC 0065-0426-36

Moderate DRY EYE SYMPTOM RELIEF

GenTeal* Tears
LUBRICANT EYE DROPS

LIQUID DROPS
Fast Soothing Relief

PREVIOUSLY TEARS NATURALE* FORTE

STERILE 15 mL (0.5 FL OZ)

Alcon[®]



GENTEAL TEARS (MODERATE)

dextran 70, glycerin, hypromellose solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0065-0426
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
Glycerin (UNII: PDC6A3C0OX) (Glycerin - UNII:PDC6A3C0OX)	Glycerin	2 mg in 1 mL

Hypromelloses (UNII: 3NXW29 V3WO) (Hypromelloses - UNII:3NXW29 V3WO)	Hypromelloses	3 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
Boric Acid (UNII: R57ZHV85D4)	
Calcium Chloride (UNII: M4I0D6 VV5M)	
Glycine (UNII: TE7660 XO1C)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Magnesium Chloride (UNII: 02F3473H9O)	
Polidronium Chloride (UNII: 6716 Z5YR3G)	
Polysorbate 80 (UNII: 6OZP39 ZG8H)	
Potassium Chloride (UNII: 660 YQ98 I10)	
Water (UNII: 059QF0 KO0R)	
Sodium Chloride (UNII: 451W47IQ8 X)	
Zinc Chloride (UNII: 86Q357L16B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0426-36	1 in 1 CARTON	03/01/2016	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:0065-0426-37	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(0065-0426)