

TEARS NATURALE FORTE - 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

OTC - ACTIVE INGREDIENT SECTION

Active Ingredients

Dextran 70 0.1%
Glycerin 0.2%
Hypromellose 0.3%

OTC - PURPOSE SECTION

Purpose

Lubricant

INDICATIONS & USAGE SECTION

Uses

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

WARNINGS SECTION

Warnings

For external use only

OTC - DO NOT USE SECTION

Do not use

- if this solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product

OTC - WHEN USING SECTION

When using this product

- remove contact lenses before using
- do not touch tip of container to any surface to avoid contamination
- replace cap after each use

OTC - STOP USE SECTION

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse or lasts more than 72 hours

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION SECTION

Directions

- Instill 1 or 2 drops in the affected eye(s) as needed.

OTHER SAFETY INFORMATION

Other Information

- store at room temperature.

INACTIVE INGREDIENT SECTION

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.

OTC - QUESTIONS SECTION

Questions?

In the U.S. call 1-800-757-9195
www.tearsnaturale.com

PRINCIPAL DISPLAY PANEL

Moderate/Severe Dry Eye

NDC 0065-0426-22

Dry Eye Protection

TEARS Naturale® FORTE

LUBRICANT EYE DROPS

15 mL
(0.5 FL OZ)
STERILE
Alcon®



TEARS NATURALE FORTE

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: 3NXW29V3WO) (Hypromelloses - UNII:3NXW29V3WO)	Hypromelloses	3 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
Boric Acid (UNII: R57ZHV85D4)	
Calcium Chloride (UNII: M4I0D6VV5M)	
Glycine (UNII: TE7660XO1C)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Magnesium Chloride (UNII: 02F3473H9O)	
Polidronium Chloride (UNII: 6716Z5YR3G)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Potassium Chloride (UNII: 660YQ98I10)	
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	
Zinc Chloride (UNII: 86Q357L16B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0426-22	15 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	01/02/2003	

Labeler - Alcon Laboratories, Inc. (008018525)

Registrant - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Laboratories, Inc.		008018525	MANUFACTURE(0065-0426)

Revised: 3/2009

Alcon Laboratories, Inc.