

TEARS NATURALE FREE - dextran 70, 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

Active Ingredients	Purpose
Dextran 70 0.1%	Lubricant
Hypromellose 2910 0.3%	Lubricant

Uses

- For the 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

- To avoid contamination, do not touch tip of container to any surface.
- Do not reuse.
- Once opened, discard.

Stop use and ask a doctor if

- you experience eye pain.
- you experience changes in vision.
- you experience continued redness or irritation of the eye.
- the 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

- Instill one or two drops in the affected eye(s) as needed.

Other information

- Store at room temperature.

Inactive Ingredients

Potassium chloride, purified water, sodium borate, sodium chloride. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions or Comments? Call Us.

In the U.S. call 1 (800) 757-9195 or visit www.tearsnaturale.com

TEARS Naturale FREE® LUBRICANT EYE DROPS PERFORMANCE GUARANTEE (see side panel)

PRINCIPAL DISPLAY PANEL

Mild/Moderate Dry Eye

Preservative Free

TEARS Naturale FREE®

LUBRICANT EYE DROPS

60 Single-Use Vials

0.9 mL (0.03 FL OZ Each)

STERILE

Alcon®

Convenience

Tears Naturale Free® Lubricant Eye Drops provide lasting relief for mild to moderate dry eye with the convenience of a vial.

Guaranteed to provide relief.

TEARS NATURALE FREE® Lubricant Eye Drops is guaranteed to provide temporary relief of dry eye symptoms. Prove it to yourself at no risk. If TEARS NATURALE FREE® Lubricant Eye Drops does not provide you with the relief you expect, you may return the unused portion with evidence of price paid to

Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, Texas 76134, for an immediate and full refund.

TAMPER EVIDENT:

Do not use if vial is damaged or opened.

© 2002, 2003, 2006, 2008, 2012 Novartis

Manufactured for:

Alcon®

ALCON LABORATORIES, INC.

FORT WORTH, TX 76134 USA
MADE IN FRANCE

427294

9008140-0512

Preservative Free

TEARS Naturale FREE®

(Dextran 70 0.1% and Hypromellose 2910 0.3%)

LUBRICANT EYE DROP

DIRECTIONS:

Make sure container is intact before use.

To open, completely TWIST off tab.

Do NOT pull off.

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

Throw away container. Do not reuse.

See more information at www.tearsnaturale.com

TEARS Naturale FREE®

LUBRICANT EYE DROPS
PERFORMANCE GUARANTEE (see side panel)

Convenience

TEARS Naturale Free® Lubricant Eye Drops provide lasting relief for mild to moderate dry eye with the convenience of a vial.

Guaranteed to provide relief.

TEARS NATURALE FREE® Lubricant Eye Drops is guaranteed to provide temporary relief of dry eye symptoms. Prove it to yourself at no risk. If TEARS NATURALE FREE® Lubricant Eye Drops does not provide you with the relief you expect, you may return the unused portion with evidence of price paid to Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, Texas 76134, for an immediate and full refund.

TAMPER EVIDENT:
Do not use if vial is damaged or opened.
© 2002, 2003, 2006, 2008, 2012 Novartis

Manufactured for:
Alcon®
ALCON LABORATORIES, INC.
FORT WORTH, TX 76134 USA
MADE IN FRANCE

427294
9008140-0512

Mild/Moderate Dry Eye



Preservative Free

TEARS Naturale FREE®

LUBRICANT EYE DROPS

60 Single-Use Vials

0.9 mL (0.03 FL OZ) Each

STERILE
Alcon®

Drug Facts

Active Ingredients	Purpose
Dextran 70 0.1%	Lubricant
Hypromellose 2910 0.3%	Lubricant

Uses

For the 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

To avoid contamination, do not touch tip of container to any surface.

Do not reuse.

Once opened, discard.

Stop use and ask a doctor if

you experience eye pain.
you experience continued redness or irritation of the eye.
the 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

Instill one or two drops in the affected eye(s) as needed.

Other Information

Store at room temperature.

Inactive Ingredients

Potassium chloride, purified water, sodium borate, sodium chloride. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions or Comments? Call Us.

In the U.S. call 1 (800) 757-9195 or visit www.tearsnaturale.com



1543



3 00650 41636 8

APPROVAL

The undersigned :

Name

Signature

confirms that this proof contains an accurate translation of the English Corporate Standard text, and is in compliance with the registered information and the legal rules.

Please also carefully check :

- local barcodes if any
- formula
- components if mentioned
- shelflife if mentioned
- storage conditions
- trademarks

This proof is approved :

- as is
- conditionally

Customer request :

- new proof

Signature and date :

FASERRICHTUNG ↑

KONSTRUKTIONSR: 323658
KUNDEN: 11007
WALDNER
MASSA 135_00
MASSH 60_00
MATERIALGABRICHT: 100
MATERIAL: 01/05
DATENSPELZ: GHU
A. FALLER KG 79183 WALDKIRCH
MACHART/ZUSCHNITT
OFFENSFORMAT: 1,414_50
LAUFLEISTUNG: 1,244_00
LAUFLEISTUNG: 1
CS MASS: 1,144_50
CS MASS: 1,144_50
FF-GES: 1,18_44_00
FEANUCHE_OCH: 634_60

See more information at www.tearsnaturale.com

Throw away container. Do not reuse.



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



Do NOT pull off.
To open, completely TWIST off tab.
It's intact before use.



PACKAGING APPROVAL

NA

Date

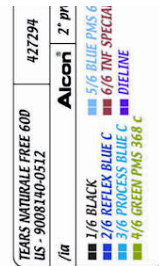
Name

Carton 135 x 60 x 81 mm
Faller 323658

001/06/2012

59 C
NO COLOR
NO VARNISH
L MIX RED

PLAN ALCON : NA
Type machine : Mono 6



TEARS NATURALE FREE

dextran 70, hypromellose 2910 solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0065-0416
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)	3 mg in 1 mL
Dextran 70 (UNII: 7SA290YK68) (Dextran 70 - UNII:7SA290YK68)	Dextran 70	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Potassium Chloride (UNII: 660YQ98I10)	
Water (UNII: 059QF0KO0R)	
Sodium Borate (UNII: 91MBZ8H3QO)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sodium Chloride (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0416-22	60 in 1 CARTON	11/01/1990	
1		.9 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:0065-0416-25	36 in 1 CARTON	11/01/1990	
2		.9 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
3	NDC:0065-0416-36	60 in 1 CARTON	03/01/2002	12/31/2005
3		.8 mL in 1 VIAL, SINGLE-DOSE; 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	11/01/1990	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Kaysersberg Pharmaceuticals		267486052	manufacture(0065-0416)

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Pharma Solutions, LLC		043911403	MANUFACTURE(0065-0416)

Revised: 6/2016

Alcon Laboratories, Inc.