SYSTANE HYDRATION PF PRESERVATIVE FREE- polyethylene glycol 400 and propylene glycol solution/ drops Alcon Laboratories, Inc.

Drug Facts

Active Ingredients	Purpose
Polyethylene Glycol 400 0.4%	Lubricant
Propylene Glycol 0.3%	Lubricant

Uses

• for use as a protectant against further irritation or to relieve dryness of the eye

Warnings

For external use only

Do not use

- if this product 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:

- 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.
- see side of carton for directions for use

Other information

store at room temperature

Inactive ingredients

aminomethylpropanol, boric acid, hydroxypropyl guar, potassium chloride, purified water, sodium borate, sodium chloride, sodium hyaluronate, sorbitol. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions?

In the U.S. call 1 (800) 757-9195

www.systane.com alcon.medinfo@alcon.com

Directions for Use:

- Hold the bottle just below the cap and twist the cap to open.
- **BEFORE FIRST USE**, hold the bottle upside down and dispense one drop of product to discard.
- Shake the bottle downward to remove residual product (see picture).



- Place 1 or 2 drops in the affected eye(s) as needed and blink.
- After use, shake the bottle downward to remove residual product that may be left on the tip (see picture above).
- Replace cap after use.

Top of Carton: SYSTANE® Lubricant Eye Drops

HYDRATION PFPRESERVATIVE-FREE DRY EYE RELIEF

Preservative-Free

PRINCIPAL DISPLAY PANEL

Preservative-Free

SYSTANE® Lubricant Eye Drops

HYDRATION PF PRESERVATIVE-FREE DRY EYE RELIEF

Extra moisturizing for sensitive eyes Longer lasting hydration*

Preservative-Free Bottle

#1 Doctor Recommended Brand¹

Alcon

STERILE 10 mL (0.34 FL OZ)

Side Panel:

TAMPER EVIDENT: For your protection, this bottle has a tamper evident ring around the bottom of the cap. Do not use if this ring is damaged or missing at the time of purchase.

¹Based on a survey of eye care professionals. Data on file. *vs SYSTANE® ULTRA Lubricant Eye Drops

Alcon Laboratories, Inc. Fort Worth, TX 76134 USA Country of Origin: USA www.alconpatents.com

300059080-1022



Top of Carton: SYSTANE® Lubricant Eye Drops

HYDRATION PFPRESERVATIVE-FREE
DRY EYE RELIEF

PRINCIPAL DISPLAY PANEL

Preservative-Free Bottle

SYSTANE® Lubricant Eye Drops

HYDRATION PF PRESERVATIVE-FREE DRY EYE RELIEF

Extra moisturizing for sensitive eyes Longer lasting hydration*

#1 Doctor Recommended Brand¹

Hydro Boost Technology

Alcon

STERILE 10 mL (0.34 FL OZ)

Side Panel:

TAMPER EVIDENT:

For your protection, this bottle has a tamper evident ring around the bottom of the cap. Do not use if this ring is damaged or missing at the time of purchase.

¹Based on a survey of eye care professionals. Data on file. *vs SYSTANE® ULTRA Lubricant Eye Drops

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300046319-0521



SYSTANE® Lubricant Eye Drops

HYDRATION PF PRESERVATIVE-FREE DRY EYE RELIEF

STERILE

10mL (0.34 FL OZ)

Only for use in the eye.

Store at room temperature.

TAMPER EVIDENT: For your protection, this bottle has a tamper evident ring around the bottom of the cap. Do not use if this ring is damaged or missing at the time of purchase.

Alcon Laboratories, Inc. Fort Worth, TX 76134 USA

See Carton for Directions For Use.

Country of Origin: USA

LOT: EXP:

300051436-0921



SYSTANE HYDRATION PF PRESERVATIVE FREE

polyethylene glycol 400 and propylene glycol solution/ drops

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0065-1510	
Route of Administration	OPHTHALMIC			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Polyethylene Glycol 400 (UNII: B697894SGQ) (Polyethylene Glycol, Unspecified - UNII: 3MJQ0SDW1A)	Polyethylene Glycol 400	4 mg in 1 mL		
Propylene Glycol (UNII: 6DC9Q167V3) (Propylene Glycol - UNII:6DC9Q167V3)	Propylene Glycol	3 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
Aminomethylpropanol (UNII: LU49E6626Q)				
Boric Acid (UNII: R57ZHV85D4)				
Guaraprolose (3500 Mpa.S At 1%) (UNII: 3A1I7376TC)				
Potassium Chloride (UNII: 660YQ98I10)				
Water (UNII: 059QF0KO0R)				
Sodium Borate (UNII: 91MBZ8H3QO)				

Sodium Chloride (UNII: 451W47IQ8X)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sorbitol (UNII: 506T60A25R)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0065-1510- 06	1 in 1 CARTON	02/01/2021		
1		10 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:0065-1510- 00	2 in 1 CARTON	01/11/2023		
2		10 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Mark				
OTC Monograph Drug	M018	02/01/2021		

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment			
Name	Address	ID/FEI	Business Operations
Alcon Research, LLC		007672236	manufacture(0065-1510)

Establishment				
Name	Address	ID/FEI	Business Operations	
S.A. Alcon-Couvreur N.V.		370205429	manufacture(0065-1510)	

Revised: 11/2023 Alcon Laboratories, Inc.