SYSTANE ULTRA- polyethylene glycol 400 and propylene glycol 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***
Polyethylene Glycol 400 0.4%	Lubricant
Propylene Glycol 0.3%	Lubricant

Uses

- For the temporary relief of burning and irritation due to 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
- do not reuse
- once opened, discard

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse, persists or lasts 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 1 or 2 drops in the affected eye(s) as needed.

Other Information

- Store at room temperature

Inactive Ingredients

Aminomethylpropanol, boric acid, hydroxypropyl guar, potassium chloride, purified water, sodium chloride, 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

PRINCIPAL DISPLAY PANEL

CONVENIENT PRESERVATIVE-FREE **VIALS**

#1 Doctor Recommended Brand[1]
Systane® ULTRA
LUBRICANT EYE DROPS

HIGH PERFORMANCE

EXTENDED PROTECTION
FAST SYMPTOM RELIEF
PRESERVATIVE-FREE VIALS

STERILE
60 Vials 0.7 mL Each

Alcon®
A Novartis company

Systane® ULTRA
LUBRICANT EYE DROPS

← SEE DETAILS ON SIDE PANEL

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Systane® ULTRA
LUBRICANT EYE DROPS

HIGH PERFORMANCE

EXTENDED PROTECTION
FAST SYMPTOM RELIEF
PRESERVATIVE-FREE VIALS

60 STERILE Vials 0.7 mL Each

Alcon® a Novartis company

Open your eyes to a breakthrough in comfort with SYSTANE® ULTRA Lubricant Eye Drops.

SYSTANE® ULTRA preservative-free vials elevates the science of dry eye therapy to a new level so you can have relief from dry eye anytime, anywhere.

From first blink, eyes feel lubricated and refreshed. Feel the difference in dry eye relief with SYSTANE® ULTRA.

TAMPER EVIDENT:
Do not use if vial is damaged or opened.

Made in France
U.S. Patent Nos. 6,403,609, 6,583,124 and 6,838,449.

Alcon®
Alcon Laboratories, Inc.
Fort Worth, Texas 76134 USA

[1]Survey of Ophthalmologists and Optometrists, Harris Interactive®, December 2008.

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LOT:

EXP.:

Throw away container. Do not reuse.

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

DIRECTIONS
Make sure container is intact before use
To open
COMPLETELY TWIST OFF TAB
Do not pull off

SYSTANE ULTRA

polyethylene glycol 400 and propylene glycol solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0065-1432
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Polyethylene Glycol 400 (UNII: B697894SGQ) (Polyethylene Glycol, Unspecified - UNII:3WJQ0SDW1A)	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)	
GUAR GUM (UNII: E89I1637KE)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-1432-01	24 in 1 CARTON	07/27/2009	12/31/2017
1		0.4 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0065-1432-02	4 in 1 CARTON	07/27/2009	12/31/2017
2		0.4 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:0065-1432-03	72 in 1 CARTON	07/27/2009	12/31/2017
3		0.4 mL in 1 VIAL; Type 0: Not a Combination Product		
4	NDC:0065-1432-04	5 in 1 CARTON	07/27/2009	
4		.7 mL in 1 VIAL; Type 0: Not a Combination Product		

5	NDC:0065-1432-05	60 in 1 CARTON	07/27/2009	
5		.7 mL in 1 VIAL; Type 0: Not a Combination Product		
6	NDC:0065-1432-06	25 in 1 CARTON	07/27/2009	
6		.7 mL in 1 VIAL; 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	07/27/2009	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Kaysersberg Pharmaceuticals		267486052	manufacture(0065-1432)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoire Unither		574139809	manufacture(0065-1432)

Revised: 12/2018 Alcon Laboratories, Inc.