

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
- for temporary relief of discomfort due to minor irritation of the eye or to exposure to wind or sun

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 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.

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.systeme.com

PRINCIPAL DISPLAY PANEL

Systeme®

LUBRICANT EYE DROPS

ULTRA PF

PRESERVATIVE-FREE

DRY EYE RELIEF

Convenient Single Vials On-The-Go

Great for sensitive eyes

Fast-acting hydration
and lasting relief

Moisture-rich formula

#1 Doctor Recommended Brand¹

STERILE

60 Vials 0.7 mL Each

Alcon

SIDE DISPLAY PANEL

Systeme®

LUBRICANT EYE DROPS

ULTRA PF

PRESERVATIVE-FREE

DRY EYE RELIEF

Convenient Single Vials On-The-Go

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 at time of purchase.

¹Based on a survey of eye care professionals. Data on file.

www.alconpatents.com
Made in France

W435221-0919

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LUBRICANT EYE DROPS

ULTRA PF
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DRY EYE RELIEF

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DOCTOR RECOMMENDED BRAND #1

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

Put 1 or 2 drops in the affected eye(s) as needed.
Throw away container.
Do not reuse.

Manufactured for:
Alcon
Alcon Laboratories, Inc.
Fort Worth, TX 76134 USA

Drug Facts	
Active ingredients	Purpose
Polyethylene Glycol 400 0.4%	Lubricant
Propylene Glycol 0.2%	Lubricant
Uses	
■ for the temporary relief of burning and irritation due to dryness of the eye	
■ 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 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 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	
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 alcon.medinfo@alcon.com www.systane.com	

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	

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.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: 12/2022

Alcon Laboratories, Inc.