

**SYSTANE ULTRA- polyethylene glycol 400 and propylene glycol solution/
drops**

Alcon Laboratories, Inc.

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
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.systane.com

PRINCIPAL DISPLAY PANEL

Systane®
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

Systane®
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

Systane®
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.

¹ Based on a survey of eye care professionals. Data on file.
www.alconpatents.com
Made in France

Systane®
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 BRAND

Alcon

STERILE
60 Vials (0.7 mL Each)

Systane®
LUBRICANT EYE DROPS

ULTRA PF
PRESERVATIVE-FREE
DRY EYE RELIEF

Convenient
Single Vials
On-the-Go

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 76154 USA

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 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	
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 Drug	M018	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: 12/2023

Alcon Laboratories, Inc.