

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 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
- 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

- shake well before using
- 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, POLYQUAD® (polyquaternium-1) 0.001% preservative, 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

PRINCIPAL DISPLAY PANEL

Systane®

LUBRICANT EYE DROPS

**ULTRA
HIGH PERFORMING
DRY EYE RELIEF**

Fast-acting hydration
and lasting relief
Moisture rich formula

#1 Doctor Recommended Brand¹

Alcon STERILE
10mL (1/3 FL OZ)

SIDE PANEL:

TAMPER EVIDENT: For your protection, this bottle has an imprinted seal around the neck. Do not use if seal is damaged or missing at time of purchase.

U.S. Pat.: www.alconpatents.com
Country Of Origin: Singapore

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

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

ACTUAL SIZE

Alcon
Alcon Laboratories, Inc.
Fort Worth, TX 76134 USA

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

300068356-0924



Systane®
LUBRICANT EYE DROPS

**ULTRA
HIGH PERFORMING
DRY EYE RELIEF**

Fast-acting hydration
and lasting relief
Moisture rich formula

#1 Doctor Recommended Brand¹Alcon STERILE
10mL (1/3 FL OZ)

SIDE PANEL:

TAMPER EVIDENT: For your protection, this bottle has an imprinted seal around the neck. Do not use if seal is damaged or missing at time of purchase.

www.alconpatents.com
Made in USA from domestic and imported materials.

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

From first blink, eyes feel lubricated and refreshed.

Feel the difference in dry eye relief with SYSTANE® ULTRA.

ACTUAL SIZE

Alcon
Alcon Laboratories, Inc.
Fort Worth, TX 76134 USA

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

300051246-1221



SYSTANE ULTRA

polyethylene glycol 400 and propylene glycol solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0065-1431
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

Polyethylene Glycol 400 (UNII: B697894SGQ) (Polyethylene Glycol 400 - UNII:B697894SGQ)	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)	
Polidronium Chloride (UNII: 6716Z5YR3G)	
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:0065-1431-80	1 in 1 CARTON	10/01/2014	
1		3 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:0065-1431-01	1 in 1 CARTON	10/01/2014	
2		1.5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:0065-1431-05	1 in 1 CARTON	10/01/2014	
3		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
4	NDC:0065-1431-18	3 in 1 CARTON	10/01/2014	
4		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
5	NDC:0065-1431-21	1 in 1 CARTON	10/01/2014	
5		3 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
6	NDC:0065-1431-28	2 in 1 CARTON	10/01/2014	
6		4 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
7	NDC:0065-1431-31	1 in 1 CARTON	10/01/2014	
7		4 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
8	NDC:0065-1431-41	2 in 1 CARTON	10/01/2014	
8		10 mL in 1 BOTTLE, DROPPER; 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	10/01/2014	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Research LLC		007672236	manufacture(0065-1431)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Singapore Manufacturing Pte Ltd		595170137	manufacture(0065-1431)

Revised: 7/2025

Alcon Laboratories, Inc.