

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

**Alcon Laboratories, Inc.**

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## ***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
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® (polyquarternium-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](mailto:alcon.medinfo@alcon.com)

[www.systane.com](http://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 Brand<sup>1</sup>**

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.

[www.alconpatents.com](http://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

<sup>1</sup> Based on a survey of eye care professionals. Data on file.

300051205-0122



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[www.alconpatents.com](http://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.

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300051246-1221



## SYSTANE ULTRA

polyethylene glycol 400 and propylene glycol solution/ drops

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>Polyethylene Glycol 400</b> (UNII: B697894SGQ) (Polyethylene Glycol 400 - UNII:B697894SGQ)	Polyethylene Glycol 400	4 mg in 1 mL
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3) (Propylene Glycol - UNII:6DC9Q167V3)	Propylene Glycol	3 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Aminomethylpropanol</b> (UNII: LU49E6626Q)	
<b>Boric Acid</b> (UNII: R57ZHV85D4)	
<b>Guar Gum</b> (UNII: E89I1637KE)	
<b>Polidronium Chloride</b> (UNII: 6716Z5YR3G)	
<b>Potassium Chloride</b> (UNII: 660YQ98I10)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Hydrochloric Acid</b> (UNII: QTT17582CB)	
<b>Sodium Hydroxide</b> (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: 11/2023

Alcon Laboratories, Inc.