

**SYSTANE- polyethylene glycol 400 and propylene glycol gel**  
**Alcon Laboratories, Inc.**

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**Systane Gel Drops**

***Drug Facts***

<b>Active Ingredients</b>	<b>Purpose</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 use as a protectant against further irritation or to relieve 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
- replace cap after each use

**Stop use and ask a doctor if** you experience any of the following:

- you feel 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, edetate disodium, hydroxypropyl guar, POLYQUAD® (polyquaternium-1) 0.001% preservative, potassium chloride, sodium chloride, sorbitol and purified water. 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 GEL

### **GEL DROPS**

SOOTHING DRY EYE RELIEF

Long-lasting formula  
Day or night protection

#1 DOCTOR RECOMMENDED BRAND<sup>1</sup>  
LIQUID GEL

STERILE  
10mL (1/3 FL OZ)

**Alcon**

## **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)

Made in USA from domestic and imported materials

Indulge your eyes in this easy-to-use droppable gel. Systane® GEL DROPS forms a protective shield over your eyes to provide enduring relief day or night.

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

300048642-0621

## Alcon

Alcon Laboratories, Inc.  
Fort Worth, TX 76134 USA



## SYSTANE

polyethylene glycol 400 and propylene glycol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0065-0454
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>Guaraprolose (3500 Mpa.S At 1%)</b> (UNII: 3A1I7376TC)	
<b>Polidronium Chloride</b> (UNII: 6716Z5YR3G)	
<b>Potassium Chloride</b> (UNII: 660YQ98I10)	
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Water</b> (UNII: 059QF0KO0R)	
<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:0065-0454-07	10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/11/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M018	02/09/2011	

**Labeler** - Alcon Laboratories, Inc. (008018525)

**Registrant** - Alcon Laboratories, Inc. (008018525)

### Establishment

Name	Address	ID/FEI	Business Operations
Alcon Research LLC		007672236	manufacture(0065-0454)

