

**SYSTANE- polyethylene glycol and propylene glycol solution/ drops**  
**Alcon Research Ltd**

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**Systane**  
**Lubricant Eye Drops**

**Active Ingredients**

<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

**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**

- instill 1 or 2 drops in the affected eye(s) as needed

### **Other Information**

- store at room temperature
- protect from light

### **Inactive Ingredients**

boric acid, calcium chloride, hydroxypropyl guar, magnesium chloride, potassium chloride, purified water, sodium chloride, zinc chloride. 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

**ORIGINAL PF  
PRESERVATIVE-FREE  
DRY EYE RELIEF**

Convenient  
Single Vials  
***On-the-Go***

Great for Sensitive Eyes  
Refreshes & Lubricates  
Soothing Comfort

**#1 Doctor Recommended Brand<sup>1</sup>**

**STERILE**

**30** Vials 0.7 mL Each

**Alcon**

**Side Panel (s)**

**SOOTHING COMFORT**

SYSTANE® Original PF  
Lubricant Eye Drops is scientifically  
formulated to shield eyes from  
dry eye discomfort so that  
eyes feel refreshed.

**LONG-LASTING RELIEF**

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SYSTANE® Original PF  
Lubricant Eye Drops provides  
long-lasting dry eye relief.

**PRESERVATIVE-FREE**

SYSTANE® Original PF  
Lubricant Eye Drops comes in  
convenient preservative-free vials  
so you can enjoy relief from dry  
eye anytime, anywhere.

**TAMPER EVIDENT:** Do not use if vial is  
damaged or opened at time of purchase.

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

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

Made in France

435241-0819

**Systane®**  
LUBRICANT EYE DROPS

**ORIGINAL PF**  
PRESERVATIVE-FREE  
DRY EYE RELIEF

**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

**Systane**  
LUBRICANT EYE DROPS

**ORIGINAL PF**  
PRESERVATIVE-FREE  
DRY EYE RELIEF

Convenient  
Single Vials  
On-the-Go



**SOOTHING COMFORT**

SYSTANE® Original PF Lubricant Eye Drops is scientifically formulated to shield eyes from dry eye discomfort so that eyes feel refreshed.

**LONG-LASTING RELIEF**

SYSTANE® Original PF Lubricant Eye Drops provides long-lasting dry eye relief.

**PRESERVATIVE-FREE**

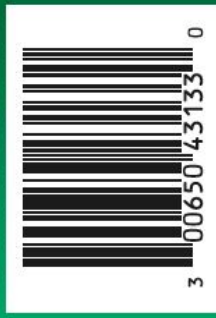
SYSTANE® Original PF Lubricant Eye Drops comes in convenient preservative-free vials so you can enjoy relief from dry eye anytime, anywhere.

**TAMPER EVIDENT:** Do not use if vial is damaged or opened at time of purchase.

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Convenient  
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Great for Sensitive Eyes  
Refreshes & Lubricates  
Soothing Comfort



**Alcon**

30 Vials (0.7 mL Each) STERILE

**Systane**  
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**ORIGINAL PF**  
PRESERVATIVE-FREE  
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Alcon Laboratories, Inc.  
Fort Worth, TX 76134 USA

LOT :  
EXP. :

435241

# Drug Facts

Active Ingredients	Purpose
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**Inactive ingredients** boric acid, calcium chloride, hydroxypropyl guar, magnesium chloride, potassium chloride, purified water, sodium chloride, zinc chloride. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

**Questions?**  
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 alcon.medinfo@alcon.com www.systane.com

## SYSTANE

polyethylene glycol and propylene glycol solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0065-0431
<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, Unspecified -	Polyethylene Glycol	4 mg

UNII:3WJQ0SDW1A)	400	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>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>CALCIUM CHLORIDE</b> (UNII: M4I0D6VV5M)	
<b>GUAR GUM</b> (UNII: E89I1637KE)	
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)	
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B)	
<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:0065-0431-04	4 in 1 CARTON	10/30/2015	12/31/2017
1		0.4 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0065-0431-32	28 in 1 CARTON	10/30/2015	12/31/2017
2		0.4 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:0065-0431-57	40 in 1 CARTON	10/30/2015	12/31/2017
3		0.4 mL in 1 VIAL; Type 0: Not a Combination Product		
4	NDC:0065-0431-33	30 in 1 CARTON	10/30/2015	
4		0.7 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	10/30/2015	

**Labeler** - Alcon Research Ltd (008018525)

### Establishment

Name	Address	ID/FEI	Business Operations
Kaysersberg Pharmaceuticals		267486052	manufacture(0065-0431)

