SYSTANE ULTRA - polyethylene glycol 400 and propylene glycol solution/ drops
Alcon Laboratories, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

OTC - ACTIVE INGREDIENT SECTION

Polyethylene Glycol 400 0.4%
Propylene Glycol 0.3%

OTC - PURPOSE SECTION

Lubricant

INDICATIONS & USAGE SECTION

- For the temporary relief of burning and irritation due to dryness of the eye

WARNINGS SECTION

For external use only.

OTC - DO NOT USE SECTION

Do not use

- if this product changes color or becomes cloudy
- if you are sensitive to any ingredient in this product

OTC - WHEN USING SECTION

When using this product

- do not touch tip of container to any surface to avoid contamination
- replace cap after each use

OTC - STOP USE SECTION

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse, persists or lasts more than 72 hours

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

If swallowed, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION SECTION

- Shake well before using.

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

OTHER SAFETY INFORMATION

- Store at room temperature.

INACTIVE INGREDIENT SECTION

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.

OTC - QUESTIONS SECTION

In the U.S. call **1-800-757-9195**
www.systane.com
MedInfo@AlconLabs.com

PRINCIPAL DISPLAY PANEL

Systane®
ULTRA
LUBRICANT EYE DROPS

HIGH PERFORMANCE

EXTENDED PROTECTION
FAST SYMPTOM RELIEF

#1 Doctor
Recommended
Brand[1]

Alcon®

STERILE
10 mL (FL OZ)

9006416-0111

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:0065-1431-05	1 in 1 CARTON		
1		10 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	11/30/2009	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Laboratories, Inc.		008018525	MANUFACTURE(0065-1431)

Revised: 6/2011 Alcon Laboratories, Inc.