SYSTANE - polyethylene glycol 400 and propylene glycol gel
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.

Systane Gel Drops

Drug Facts

Active Ingredients	**Purpose**
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
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[1]
LIQUID GEL

STERILE
10mL (1/3 FL OZ)

Alcon

SYSTANE

polyethylene glycol 400 and propylene glycol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0065-0454
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)	
Edetate Disodium (UNII: 7FLD91C86K)	
Guar Gum (UNII: E89I1637KE)	
Polidronium Chloride (UNII: 6716Z5YR3G)	
Potassium Chloride (UNII: 660YQ98I10)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0KO0R)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (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 final	part349	02/09/2011	

Labeler - Alcon Laboratories, Inc. (008018525)

Registrant - Alcon Laboratories, Inc. (008018525)

Establishment

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

Revised: 12/2018 Alcon Laboratories, Inc.