SYSTANE BALANCE - propylene glycol emulsion
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® BALANCE Lubricant Eye Drops

Drug Facts

Active Ingredient	***Purpose***
Propylene Glycol 0.6%	Lubricant

Uses
- for the temporary relief of burning and irritation due to dryness of the eye
- for use as a lubricant to prevent further irritation or to relive dryness of the eye

Warnings

For external use only

Do not use
- if this product changes color
- 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:

boric acid, dimyristoyl phosphatidylglycerol, edetate disodium, hydroxypropyl guar, mineral oil, polyoxyl 40 stearate, POLYQUAD® (polyquaternium-1) 0.001% preservative, sorbitan tristearate, 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 DROPS

BALANCE

Restoring
Dry Eye Relief

Locks in moisture
Tear evaporation protection
Clinically proven

DOCTOR RECOMMENDED #1 BRAND[1]

Alcon
STERILE
10 mL (1/3 FL OZ)

LOT: EXP.:

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

Made in USA from domestic and imported materials

Systane®
BALANCE
Lubricant
Eye
Drops
restores the
natural tear's
lipid layer to
lock in moisture
and protect
against tear
evaporation.

ACTUAL SIZE

Alcon
Alcon Laboratories, Inc.
Fort Worth, TX 76134 USA

[1] Based on a survey of eye care professionals. Data on file.

300048644-0521

SYSTANE BALANCE

propylene glycol emulsion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0065-1433
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of**	**Strength**

Ingredient Name	Strength	Strength
Propylene Glycol (UNII: 6DC9Q167V3) (Propylene Glycol - UNII:6DC9Q167V3)	Propylene Glycol	0.06 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Boric Acid (UNII: R57ZHV85D4)	
Dimyristoylphosphatidylglycerol, DI- (UNII: BI71WT9P3R)	
Edetate Disodium (UNII: 7FLD91C86K)	
Guar Gum (UNII: E89I1637KE)	
Mineral Oil (UNII: T5L8T28FGP)	
Polyoxyl 40 Stearate (UNII: 13A4J4NH9I)	
Sorbitan Tristearate (UNII: 6LUM696811)	
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0KO0R)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Polidronium Chloride (UNII: 6716Z5YR3G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-1433-02	1 in 1 CARTON	07/27/2010	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:0065-1433-07	2 in 1 CARTON	07/27/2010	
2		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:0065-1433-11	1 in 1 CARTON	07/27/2010	
3		1.5 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 final	part349	07/27/2010	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Research LLC		007672236	manufacture(0065-1433)