SYSTANE - hypromellose 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.

Drug Facts

Active ingredient	***Purpose***
Hypromellose (0.3%)	Lubricant

Uses

- for the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun
- for use as a protectant against further irritation or to relieve dryness of the eye

Warnings

For external use only

Do not use

- if gel 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
- 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

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

Other information

store between 15^{o} – 30^{o}C (59^{o} – 86^{o}F)

Inactive ingredients

carbopol 980, phosphonic acid, purified water, sodium perborate and sorbitol. May contain sodium

hydroxide to adjust pH.

Questions?

In the U.S. call toll-free
1-866-393-6336
alcon.medinfo@alcon.com

TAMPER EVIDENT: For your protection, useonly if pull tab is intact attime of purchase.

PRINCIPAL DISPLAY PANEL

NDC 0065047401

Systane® GEL
LUBRICANT EYE GEL

NIGHTTIME PROTECTION
Delivers long-lasting relief of dry eye symptoms

Alcon®

STERILE
10g (0.34 FL OZ)

SYSTANE

hypromellose gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0065-0474

Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hypromellose 2910 (4000 Mpa.s) (UNII: RN3152OP35) (Hypromellose 2910 (4000 Mpa.s) - UNII:RN3152OP35)	Hypromellose 2910 (4000 Mpa.s)	3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Carbomer Homopolymer Type C (allyl Pentaerythritol Crosslinked) (UNII: 4Q93RCW27E)	
Phosphonic Acid (UNII: 35V6A8JW8E)	
Water (UNII: 059QF0KO0R)	
Sodium Perborate (UNII: Y52BK1W96C)	
Sorbitol (UNII: 506T60A25R)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0474-01	1 in 1 CARTON	12/15/2012	
1		10 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0065-0474-02	1 in 1 CARTON	12/15/2012	12/31/2018
2		3.5 g in 1 TUBE; 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	12/15/2012	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	manufacture(0065-0474) , label(0065-0474) , pack(0065-0474)

Establishment

Name	Address	ID/FEI	Business Operations
Excelvision		274234566	manufacture(0065-0474) , label(0065-0474) , pack(0065-0474)

Establishment

Name	Address	ID/FEI	Business Operations
SERVIPACK		571772875	label(0065-0474) , pack(0065-0474)