SYSTANE- hypromellose gel Alcon Laboratories, Inc.

Drug Facts

Active ingredient	Purpose
Hypromellose (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 using

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 at room temperature

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 1-800-757-9195 alcon.medinfo@alcon.com www.systane.com

PRINCIPAL DISPLAY PANEL

Systane® LUBRICANT EYE GEL

NIGHT GEL

COMFORTING DRY EYE RELIEF

Long lasting gel for nighttime use

Soothing relief

#1 DOCTOR RECOMMENDED BRAND1

GEL

Alcon

STERILE 10g (0.35 OZ)

TAMPER EVIDENT: For your protection, use only if pull tab is intact at time of purchase.

www.alconpatents.com

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

Processed in France with US-origin active ingredient for: Alcon Laboratories, Inc. Fort Worth, TX 76134 USA

25368501-0519



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 (4000 Mpa.s)

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)

P	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 Application Number or Monog Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M018	12/15/2012	

Labeler - Alcon Laboratories, Inc. (008018525)

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)

Revised: 12/2023 Alcon Laboratories, Inc.