

SYSTANE - polyethylene glycol and propylene glycol solution/ drops
Alcon Research Ltd

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
Lubricant Eye Drops

Active Ingredients

| <i>Active Ingredients</i> | <i>Purpose</i> |
|------------------------------|----------------|
| 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

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
- do not reuse
- once opened, discard

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

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

Other Information

- store at room temperature
- protect from light

Inactive Ingredients

boric acid, calcium chloride, hydroxypropyl guar, magnesium chloride, potassium chloride, purified water, sodium chloride, zinc chloride. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions?

In the U.S. call 1-800-757-9195
www.systane.com

Principal Display Panel

CONVENIENT PRESERVATIVE-FREE VIALS

#1 Doctor Recommended Brand¹
Systane[®]
LUBRICANT EYE DROPS

PRESERVATIVE-FREE VIALS

LONG LASTING RELIEF
SOOTHING COMFORT
DRY EYE THERAPY

STERILE
30 Vials 0.7 mL Each

Alcon[®]
a Novartis company

Systane[®]

LUBRICANT EYE DROPS

CONVENIENT
PRESERVATIVE-FREE
VIALS

←SEE DETAILS ON SIDE PANEL

#1 Doctor
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Brand¹

CONVENIENT
PRESERVATIVE-FREE
VIALS

Systane[®]

LUBRICANT EYE DROPS

PRESERVATIVE-FREE VIALS

LONG LASTING RELIEF
SOOTHING COMFORT
DRY EYE THERAPY

30 STERILE
Vials 0.7 mL Each

Alcon[®]
a Novartis company

ALL-DAY COMFORT.

Say good-bye to gritty, burning, dry eye discomfort. SYSTANE[®] Lubricant Eye Drops forms a unique soft gel shield to keep eyes feeling fresh and moist all day long.

LONG-LASTING RELIEF.

SYSTANE[®] Lubricant Eye Drops provides soothing relief that lasts and lasts.

PRESERVATIVE-FREE AND EASY.

SYSTANE[®] Lubricant Eye Drops comes in convenient, preservative-free vials, so you can enjoy freedom from dry eye symptoms anytime, anywhere.

Guaranteed.

SYSTANE[®] Lubricant Eye Drops is guaranteed to deliver long-lasting relief from your dry eye symptoms. Prove it to yourself at no risk.

If SYSTANE[®] Lubricant Eye Drops does not provide you with the relief you expect, we will send you a full refund, if you return the unused portion with evidence of price paid to:

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134
*No immediate and full refund

TAMPER EVIDENT:

Do not use if vial is damaged or opened.

Made in France
U.S. Patent Nos. 6,403,609
6,583,124 and
6,838,449 © 2009, 2016
Novartis

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

Alcon[®]

Alcon Laboratories, Inc.
Fort Worth, Texas 76134 USA

Drug Facts

Active Ingredients . . . Purpose

Polyethylene Glycol
490 0.4% Lubricant
Propylene Glycol
0.3% Lubricant

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www.systane.com



LOT:

EXP:

435240



Throw away container. Do not reuse.

the affected eye(s)
as needed.





SYSTANE

polyethylene glycol and propylene glycol solution/ drops

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0065-0431 |
| Route of Administration | OPHTHALMIC | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------|--------------|
| Polyethylene Glycol 400 (UNII: B697894SGQ) (Polyethylene Glycol, Unspecified - UNII:3WJQ0SDW1A) | 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 |
|--|----------|
| BORIC ACID (UNII: R57ZHV85D4) | |
| CALCIUM CHLORIDE (UNII: M410D6VV5M) | |
| GUAR GUM (UNII: E89I1637KE) | |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) | |
| POTASSIUM CHLORIDE (UNII: 660YQ98110) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| ZINC CHLORIDE (UNII: 86Q357L16B) | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0065-0431-04 | 4 in 1 CARTON | 08/14/2009 | 12/31/2017 |
| 1 | | 0.4 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | | |
|---|------------------|---|------------|------------|
| 2 | NDC:0065-0431-32 | 28 in 1 CARTON | 10/30/2015 | 12/31/2017 |
| 2 | | 0.4 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:0065-0431-57 | 40 in 1 CARTON | 08/14/2009 | 06/30/2011 |
| 3 | | 0.4 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 4 | NDC:0065-0431-33 | 30 in 1 CARTON | 10/30/2015 | |
| 4 | | 0.7 mL in 1 VIAL; 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 | 08/14/2009 | |

Labeler - Alcon Research Ltd (008018525)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| Kaysersberg Pharmaceuticals | | 267486052 | manufacture(0065-0431) |

Revised: 12/2018

Alcon Research Ltd