

FAMILY CARE PRESERVATIVE FREE SINGLE USE- polyethylene glycol 400, and propylene glycol solution/ drops

United Exchange Corp.

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.

Family Care Single Use Lubricant Eye Drops 5ct NBE Systane (581)

| 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

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 feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse, persists or lasts 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

Inactive ingredients

aminomethylpropanol, boric acid, hydrochloric acid, hydroxyethyl cellulose, potassium chloride, sodium chloride, sodium hydroxide, sorbitol, water for injection

Distributed by:

United Exchange Corp.

17211 Valley View Ave.

Cerritos, CA 90703 U.S.A.

Made in South Korea



FAMILY CARE PRESERVATIVE FREE SINGLE USE

polyethylene glycol 400, and propylene glycol solution/ drops

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:65923-581 |
| 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) | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP) | |
| POTASSIUM CHLORIDE (UNII: 660YQ98110) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:65923-581-05 | 5 in 1 BOX | 03/18/2016 | |
| 1 | | 0.4 mL in 1 VIAL, SINGLE-USE; 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 | 03/18/2016 | |

Labeler - United Exchange Corp. (840130579)

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