

RUGBY LUBRICATING EYE DROPS- polyethylene glycol, propylene glycol liquid

Rugby Laboratories

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.

Active ingredients

Polyethylene glycol 400 0.4%

Propylene glycol 0.3%

Purpose

Polyethylene glycol 400..... Lubricant

Propylene glycol..... 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 the tip of container to any surface to avoid contamination
- replace cap after each use

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse or lasts more than 72 hours

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away

Directions

- Instill 1 or 2 drops in the affected eye(s) as needed
- Children under 6 years of age: ask a doctor

Other information

- RETAIN THIS CARTON FOR FUTURE REFERENCE
- Store at room temperature

Inactive ingredients

Benzalkonium chloride as preservative, boric acid, calcium chloride, hypromellose, magnesium chloride, potassium chloride, purified water, sodium borate, sodium chloride, zinc chloride.



RUGBY LUBRICATING EYE DROPS

polyethylene glycol, propylene glycol liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1219 |
| 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 | 0.4 g in 100 mL |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3) | PROPYLENE GLYCOL | 0.3 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |

| | |
|--|--|
| BORIC ACID (UNII: R57ZHV85D4) | |
| CALCIUM CHLORIDE (UNII: M4I0D6VV5M) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) | |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BORATE (UNII: 91MBZ8H3QO) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| ZINC CHLORIDE (UNII: 86Q357L16B) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0536-1219-94 | 1 in 1 BOX | 02/19/2019 | |
| 1 | | 15 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 | 02/19/2019 | |

Labeler - Rugby Laboratories (079246066)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---|
| KC Pharmaceuticals, Inc. | | 174450460 | manufacture(0536-1219) , pack(0536-1219) , label(0536-1219) |