

**RUGBY POLYVINYL ALCOHOL 1.4% LUBRICATING EYE DROPS- polyvinyl alcohol solution/ drops**  
**Rugby Laboratories**

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**Rugby Polyvinyl Alcohol 1.4% Lubricating Eye Drops 15mL (PLD)**

**Active ingredient**

Polyvinyl alcohol 1.4%

**Purpose**

Lubricant

**Uses**

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

**Warnings**

For external use only

**Do not use this product if**

- solution changes color or becomes cloudy

**When using this product**

- remove contact lenses before using
- to avoid contamination, do not touch tip of container to any surface
- replace cap after using. Keep container tightly closed.

**Stop use and ask a doctor if you experience**

- eye pain
- changes in vision
- continued redness or irritation of the eye or if the condition worsens or persists for more than 72 hours

**Keep out of the reach of children.**

If accidentally swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

**Directions**

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

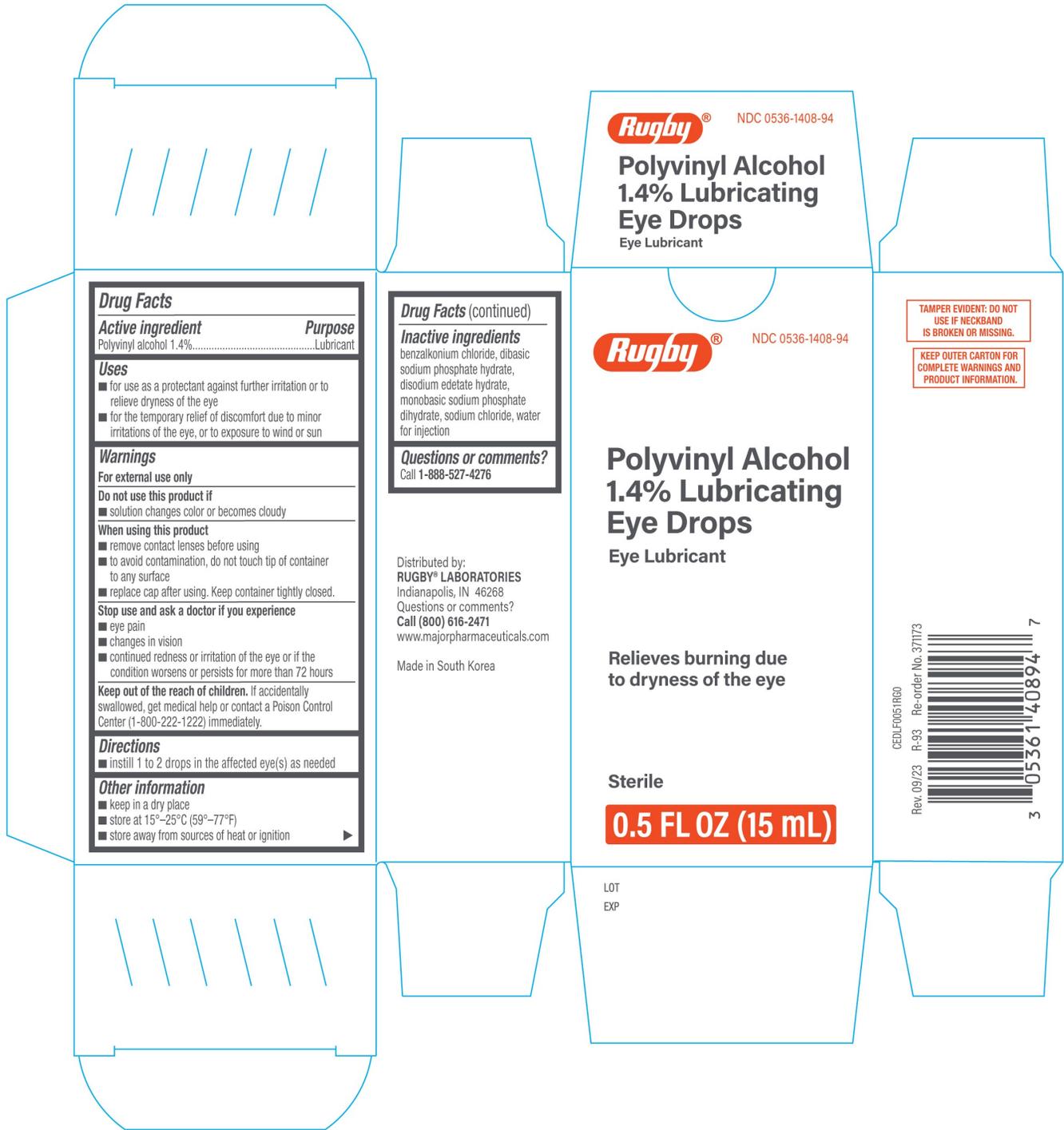
**Other information**

- keep in a dry place
- store at 15°-25°C (59°-77°F)
- store away from sources of heat or ignition

**Inactive ingredients**

benzalkonium chloride, dibasic sodium phosphate hydrate, disodium edetate hydrate, monobasic sodium phosphate dihydrate, sodium chloride, water for injection.

**Rugby Polyvinyl Alcohol 1.4% Lubricating Eye Drops 15mL**



# RUGBY POLYVINYL ALCOHOL 1.4% LUBRICATING EYE DROPS

polyvinyl alcohol solution/ drops

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0536-1408 |
| <b>Route of Administration</b> | OPHTHALMIC     |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength              | Strength           |
|---|--------------------------------|--------------------|
| <b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990) (POLYVINYL ALCOHOL, UNSPECIFIED - UNII:532B59J990) | POLYVINYL ALCOHOL, UNSPECIFIED | 1.4 g<br>in 100 mL |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>SODIUM PHOSPHATE, DIBASIC, DODECAHYDRATE</b> (UNII: E1W4N241FO) |          |
| <b>WATER</b> (UNII: 059QF0K00R)                                    |          |
| <b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)                    |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)                         |          |
| <b>SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE</b> (UNII: 5QWK665956)   |          |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                          |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0536-1408-94 | 1 in 1 BOX  | 10/19/2023           |                    |
| 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 Drug | M018                                     | 10/19/2023           |                    |

**Labeler** - Rugby Laboratories (079246066)

**Registrant** - KC Pharmaceuticals, Inc. (174450460)

### Establishment

| Name                    | Address | ID/FEI    | Business Operations   |
|-------------------------|---------|-----------|---|
| Hanlim Pharm. Co., LTD. |         | 687986034 | manufacture(0536-1408) , pack(0536-1408) , label(0536-1408) |

Revised: 10/2023

Rugby Laboratories