

**LEADER DRY EYE RELIEF EYE DROPS- glycerin, hypromellose, polyethylene glycol 400 solution/ drops**  
**Cardinal Health**

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**Leader Dry Eye Relief Eye Drops (PLD)**

***Active ingredients***

Glycerin 0.2%

Hypromellose 0.2%

Polyethylene glycol 1%

***Purpose***

Glycerin.....Lubricant

Hypromellose.....Lubricant

Polyethylene glycol 400.....Lubricant

***Uses***

- for the temporary relief of burning and irritation due to dryness of the eye
- for protection against further irritation

***Warnings***

**For external use only**

**Do not use this product** if solution changes color or becomes cloudy

**When using this product**

- to avoid contamination, do not touch tip of container to any surface. Replace cap after using.
- remove contact lens before using

**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

**If pregnant or breast-feeding**, ask a health professional before use.

**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

***Other information***

Store at 15 °-30 °C (59 °-86 °F)

***Inactive ingredients***

benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate, sodium phosphate dibasic, sodium phosphate monobasic

## Leader Dry Eye Relief Eye Drops 15mL



## Leader Dry Eye Relief Eye Drops 15mL twin pk



## LEADER DRY EYE RELIEF EYE DROPS

glycerin, hypromellose, polyethylene glycol 400 solution/ drops

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70000-0502 |
| <b>Route of Administration</b> | OPHTHALMIC     |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength           |
|---|-------------------|--------------------|
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX) | GLYCERIN          | 0.2 g<br>in 100 mL |

|   |                           |                    |
|---|---------------------------|--------------------|
| <b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO) (HYPROMELLOSE, UNSPECIFIED - UNII:3NXW29V3WO) | HYPROMELLOSE, UNSPECIFIED | 0.2 g<br>in 100 mL |
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)     | POLYETHYLENE GLYCOL 400   | 1 g<br>in 100 mL   |

### Inactive Ingredients

| Ingredient Name                                       | Strength |
|---|----------|
| <b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)       |          |
| <b>DEXTROSE</b> (UNII: IY9XDZ35W2)                    |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)            |          |
| <b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)          |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                       |          |
| <b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)          |          |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)             |          |
| <b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)              |          |
| <b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74)   |          |
| <b>SODIUM PHOSPHATE, MONOBASIC</b> (UNII: 3980JIH2SW) |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70000-0502-1 | 1 in 1 CARTON   | 04/30/2019           |                    |
| 1 |                  | 15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:70000-0502-2 | 2 in 1 CARTON   | 04/30/2019           | 07/31/2025         |
| 2 |                  | 15 mL in 1 BOTTLE, PLASTIC; 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                                     | 04/30/2019           |                    |

**Labeler** - Cardinal Health (063997360)

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

### Establishment

| Name                     | Address | ID/FEI    | Business Operations  |
|--------------------------|---------|-----------|--|
| KC Pharmaceuticals, Inc. |         | 174450460 | manufacture(70000-0502) , pack(70000-0502) , label(70000-0502) |