

FRESHKOTE PRESERVATIVE FREE LUBRICATING EYE DROPS- povidone, polyvinyl alcohol solution

FOCUS Laboratories, Inc.

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.

FreshKote Preservative Free Lubricating Eye Drops

Active Ingredients Purpose

Polyvinyl Alcohol 2.7%.....Lubricant

Povidone 2.0%.....Lubricant

Uses

- 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 if

- Seal is damaged
- Solution changes color or becomes cloudy
- You are sensitive to any ingredient in this product

Stop use and ask a doctor if

- You experience eye pain
- You experience changes in vision
- You experience continued redness or irritation
- Condition worsens
- Symptoms last 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 drop(s) in the affected eye(s) as needed

Other information

- Use before expiration date marked on container
- Store at 20-25°C(68-77°F)
- Retain this carton for future reference

Inactive ingredients

Boric acid, Edetate disodium, Ethanol, Glycerin, Phospholipids, Polysorbate 80, Potassium chloride, Purified water, Sodium chloride. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

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30 octobre 2017

étiquette 25 x 60 mm

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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:15821-108 |
| Route of Administration | OPHTHALMIC | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| POVIDONE (UNIT: E7989CH04E) (POVIDONE - UNIT:E7989CH04E) | POVIDONE | 20 g |

| | | |
|--|--------------------------------|--------------------|
| FOVIDONE (UNII: F298931B4E) (FOVIDONE - UNII:F298931B4E) | FOVIDONE | in 1000 mL |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) (POLYVINYL ALCOHOL, UNSPECIFIED - UNII:532B59J990) | POLYVINYL ALCOHOL, UNSPECIFIED | 27 g in 1000 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| BORIC ACID (UNII: R57ZHV85D4) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| POTASSIUM CHLORIDE (UNII: 660YQ98110) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:15821-108-10 | 1 in 1 BOX | 06/29/2018 | |
| 1 | | 10 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 | 06/29/2018 | |

Labeler - FOCUS Laboratories, Inc. (926378337)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|--|
| ExcelVision | | 274234566 | manufacture(15821-108) , pack(15821-108) |

Revised: 7/2018

FOCUS Laboratories, Inc.