

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: E7989.CH04E) (POVIDONE - UNIT:E7989.CH04E)	POVIDONE	20 g

FOVADONE (UNII: F298931B4E) (FOVADONE - UNII:F298931B4E)	FOVADONE	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.