

**FRESHKOTE LUBRICANT EYE DROPS- povidone/polyvinyl alcohol solution/ drops  
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 Lubricant Eye Drop**

**FreshKote Lubricant Eye Drops  
Doctor Recommended**

NDC 15821-101-15

THE CLEAR SOLUTION

Made in The USA

Sterile 15mL (0.5 FL. OZ.)

FreshKote Lubricant Eye Drops

***Drug Facts***

**Active ingredients**

**Active ingredients.....Purpose**

Polyvinyl pyrrolidone 2.0%.....Lubricant

Polyvinyl alcohol 2.7%.....Lubricant

Lubricant

**Uses**

- For use as a lubricant to prevent 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 if:**

- solution changes color or becomes cloudy.
- you are sensitive to any ingredient in this product.

**When using this product:**

- Do not touch tip of container to any surface to avoid contamination.
- Replace cap after using.

**Stop use and ask a doctor if:**

- you experience eye pain.
- you experience changes in vision.
- you experience continued redness or irritation.
- the 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) 3 or 4 times daily.

**Other information**

- Store at 15 °-30 °C (58 °-86 °F)
- Retain outer carton for full product drug facts.

**Inactive ingredients:**

Boric acid, Disodium edetate dihydrate, Ethanol, Glycerin, Lecithin, Polixetonium, Polysorbate-80, Potassium chloride, Purified water, Sodium chloride

**Questions** call toll-free 1-866-752-6006 [www.freshkote.com](http://www.freshkote.com)

Does Not Contain Benzalkonium Chloride

DO NOT USE IF IMPRINTED SEAL ON CAP IS TORN, BROKEN OR MISSING.

Manufactured for:

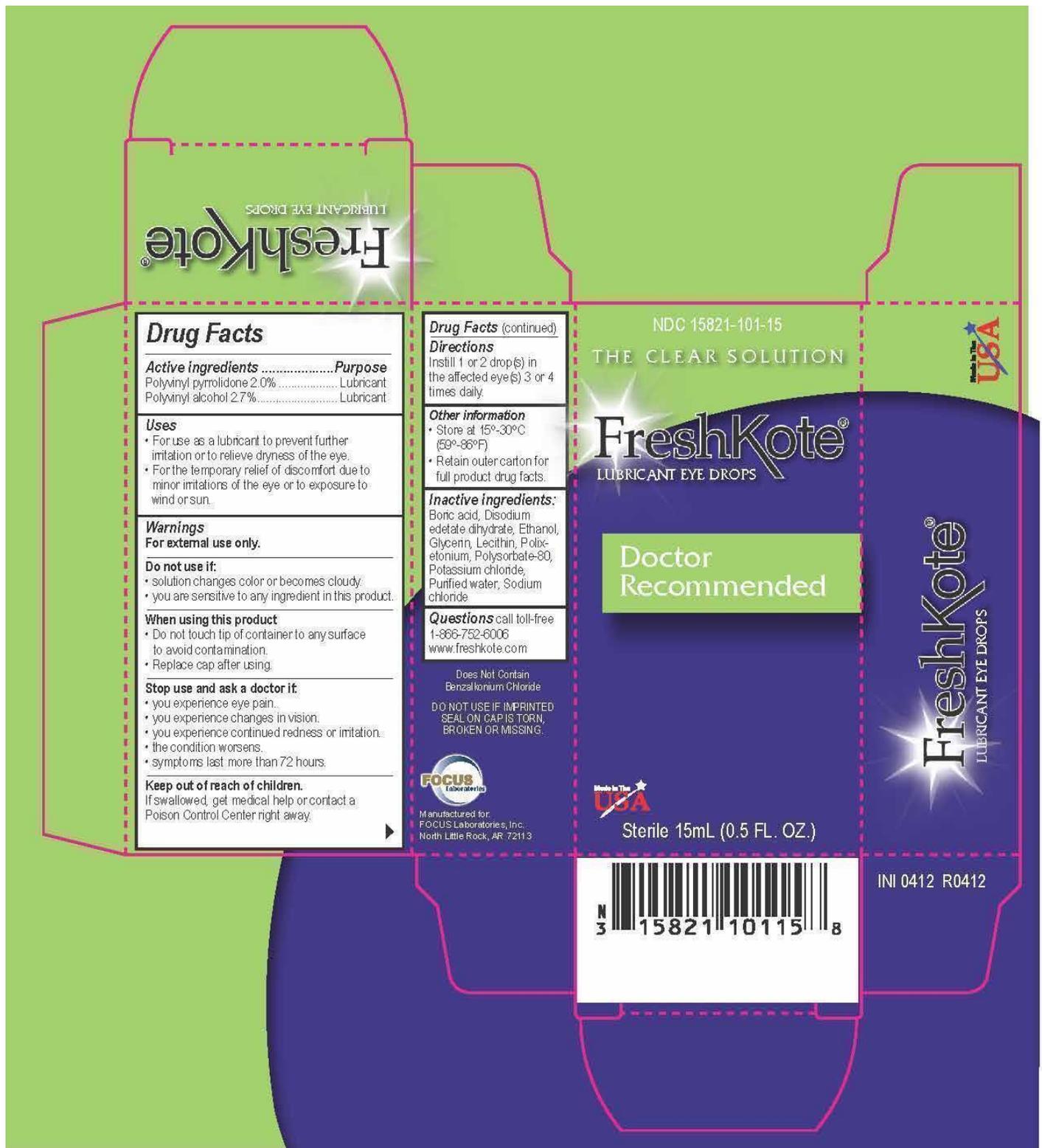
FOCUS Laboratories, Inc.

North Little Rock, AR 72113

Made in the USA

FreshKote Lubricant Eye Drops

INI0412 R0612



## FRESHKOTE LUBRICANT EYE DROPS

povidone/polyvinyl alcohol solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:15821-101
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
POVIDONE K29/32 (UNII: 390RMW2PEQ) (POVIDONE K29/32 - UNII:390RMW2PEQ)	POVIDONE K29/32	20 g in 1000 mL
POLYVINYL ALCOHOL (UNII: 532B59J990) (POLYVINYL ALCOHOL - UNII:532B59J990)	POLYVINYL ALCOHOL	27 g in 1000 mL

**Inactive Ingredients**

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
POLIXETONIUM (UNII: EJT309W86C)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15821-101-15	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/01/2006	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	04/01/2006	

**Labeler** - FOCUS Laboratories, Inc. (926378337)**Registrant** - FOCUS Laboratories, Inc. (926378337)**Establishment**

Name	Address	ID/FEI	Business Operations
Altaire Pharmaceutical		786790378	analysis(15821-101) , label(15821-101) , manufacture(15821-101) , pack(15821-101) , sterilize(15821-101)

Revised: 10/2018

FOCUS Laboratories, Inc.