

FRESHKOTE PRESERVATIVE FREE LUBRICATING EYE DROPS SINGLE USE- 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: Single Use

Active Ingredients Purpose

Polyvinyl Alcohol 2.7%.....Lubricant

Povidone 2.0%.....Lubricant

Uses

- For use as a protectant to prevent further irritation or to relieve dryness of the eye

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

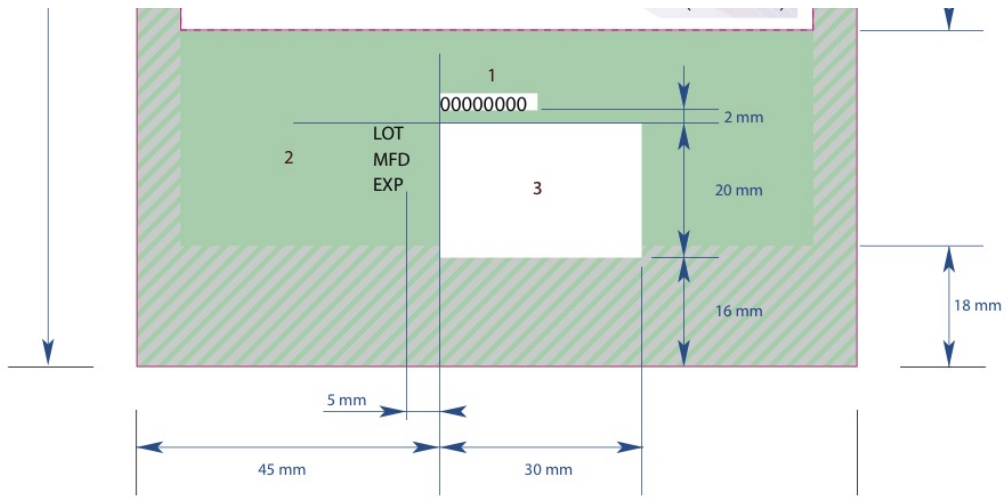
- Use before expiration date marked on container
- Store at 20-25°C(68-77°F)
- Retain this carton for future reference

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.

For the temporary relief of discomfort due to minor irritations of the eye or to exposure of wind or sun





- 1 • Our item code, read by camera.
 - News Gothic Medium, 9pt.
 - Black
 - No ink, no design, silver background
- 2 • Preprinted data's area.
- 3 • On-line printed data's area.
 - No ink, no design, silver background
- 4 • Colors, text and design allowed.
 - No ink, no design, silver background

- 1 • Notre code article lu par caméra.
 - News Gothic Medium, 9pt.
 - Noir
 - Ni encre, ni décor, fond couleur argent
- 2 • Zone de marquages pré-imprimée.
- 3 • Zone de marquages en ligne.
 - Ni encre, ni décor, fond couleur argent
- 4 • Couleur, texte and design autorisés.
 - Ni encre, ni décor, fond couleur argent

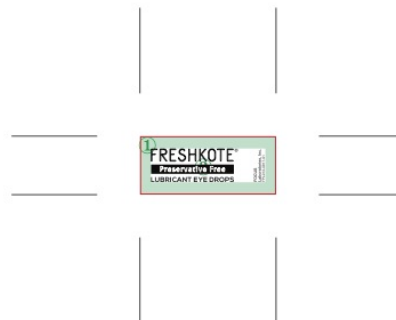
Black

Zone verte : Encre possible, pas de décor
Green area : Ink allowed, no design

Zone de soudage
Pas d'encre, aucune illustration, pas de couleur
Welding area
No ink, No artwork, No color

- ① Zone sans texte
Free text area
- ② Zone de texte 17 x 5 mm
Printing area 17 x 5 mm

Limites minimales pour l'impression
Filets isolés négatifs : 0,20mm • Filets isolés positifs : 0,15mm
Points isolés négatifs : 0,15mm • Points isolés positifs : 0,15mm
Caractères positifs : 3 points (sauf police anglaise : 4 points)
Caractères négatifs : 4 points en évitant le bold (sauf police anglaise : 5 points)



FRESHKOTE PRESERVATIVE FREE LUBRICATING EYE DROPS SINGLE USE

povidone, polyvinyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15821-105
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	20 g 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: 451W471Q8X)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15821-105-03	6 in 1 BOX	06/29/2018	
1		5 in 1 POUCH		
1		0.3 mL in 1 BOTTLE, UNIT-DOSE; 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(15821-105) , pack(15821-105)

Revised: 7/2018

FOCUS Laboratories, Inc.