

FRESHKOTE PRESERVATIVE FREE LUBRICANT EYE DROPS- povidone, polyvinyl alcohol solution solution/ drops

Harrow Eye, LLC

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 ®

Active Ingredients Purpose

Polyvinyl Alcohol 2.7%..... Lubricant

Povidone 2.0%.....Lubricant

Uses

For use as a lubricant to reduce 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

Seal is damaged
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
Shake off remaining drop before replacing cap

Stop use and ask a doctor if

You experience eye pain, changes in vision, continued redness or irritation of the eye(s), or if the condition worsens or if 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 and discard bottle 30 days after opening
Store at 20°C to 25°C (68°F to 77°F)
Retain carton for reference
Do not freeze

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.

Questions or comments?

Call toll-free +1-833-4HARROW (+1-833-442-7769)

FRESHKOTE® Preservative Free is the clear solution for the temporary relief of dry eye symptoms

HARROW

FRESHKOTE®

Preservative Free

LUBRICANT EYE DROPS

The clear solution

Temporarily Relieves Symptoms of Dry Eye

REFER TO FULL SAFETY INFORMATION PRIOR TO USE

Sterile

0.33 FL OZ (10mL)

Temporary relief from dry eye

Gentle, preservative-free drops can be used with contact lenses

Exclusive patented formulation

Unique phospholipid blend combats tear evaporation

State-of-the-art Novelia® multidose bottle dispenses drop with precision

FRESHKOTE®

Preservative Free

is the clear

solution for the

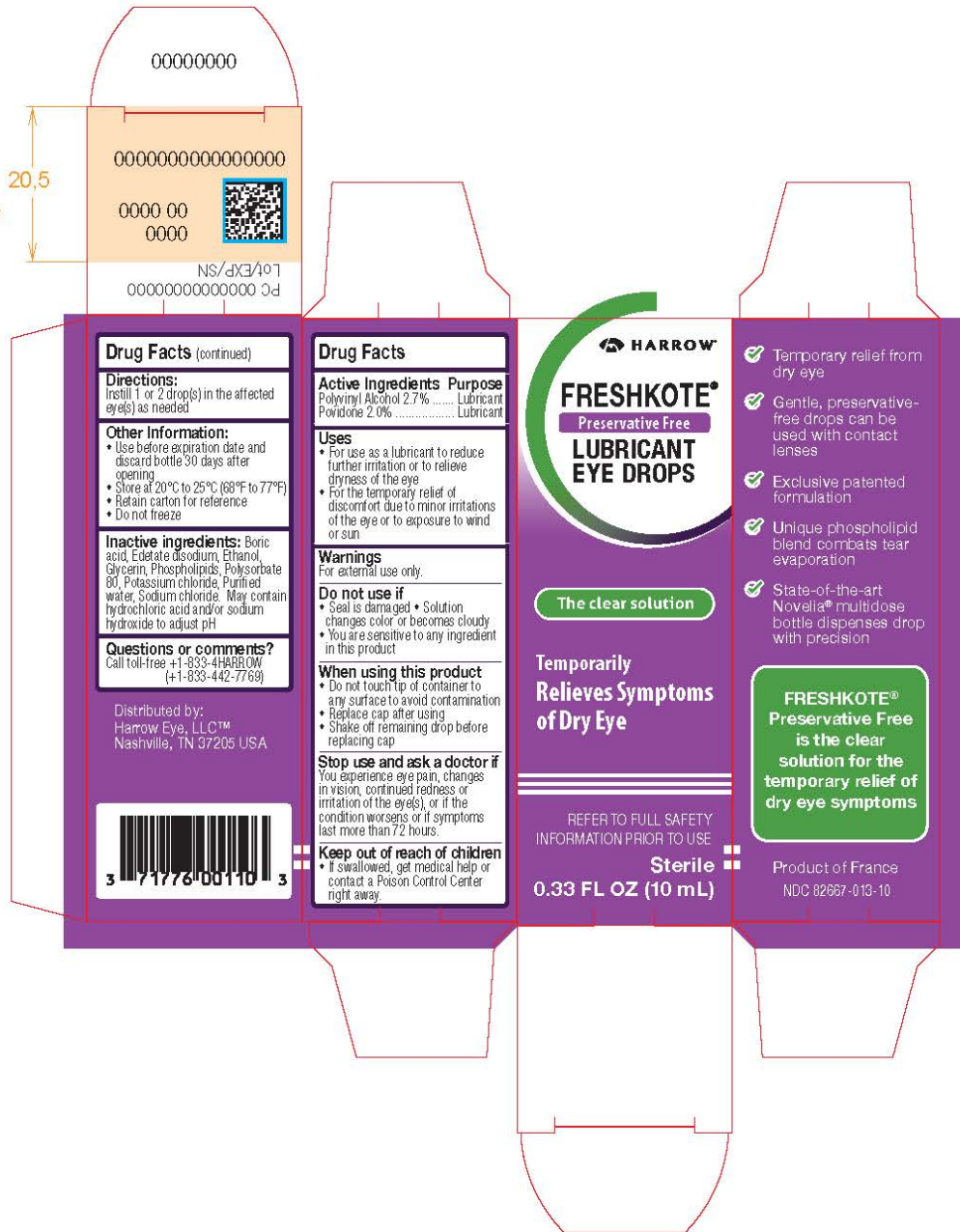
temporary relief of

dry eye symptoms

Product of France

NDC 82667-013-10

Zone non vernie
Free varnish area
28,5 x 20,5mm
Fond blanc
White background



FRESHKOTE PRESERVATIVE FREE LUBRICANT EYE DROPS

povidone, polyvinyl alcohol solution solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82667-013
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) (POLYVINYL ALCOHOL, UNSPECIFIED - UNII:532B59J990)	POLYVINYL ALCOHOL, UNSPECIFIED	27 g in 1000 mL
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	20 g in 1000 mL

Inactive Ingredients	
Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
GLYCERIN (UNII: PDC6A3C0OX)	
BORIC ACID (UNII: R57ZHV85D4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82667-013-10	1 in 1 BOX	09/15/2023	
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	09/15/2023	

Labeler - Harrow Eye, LLC (118526951)

Revised: 9/2023

Harrow Eye, LLC