

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

**Eyevance Pharmaceuticals**

-----  
**FRESHKOTE®**

**Preservative Free**

**LUBRICANT EYE DROPS**

<b>Active Ingredients</b>	<b>Purpose</b>
---------------------------	----------------

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

**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 and discard bottle 30 days after opening
- Store at 20-25 °C(68-77 °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.

## Purpose

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

## 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

<b>Drug Facts</b> (continued) <b>Directions</b> Instill 1 or 2 drop(s) in the affected eye(s) as needed <b>Other information</b> ■ Use before expiration date and discard bottle 30 days after opening ■ Store at 20-25°C (68-77°F) ■ Retain carton for reference ■ Do not freeze <b>Inactive ingredients</b> 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. <b>Questions:</b> Call toll-free 1-844-390-0720 Manufactured for: Eveance Pharmaceuticals, LLC Fort Worth, TX 76102 20011000   3 71776 00110 3	<b>Drug Facts</b> <b>Active ingredients Purpose</b> Polyvinyl alcohol 2.7%.....Lubricant Povidone 2.0%.....Lubricant <b>Uses</b> ■ 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 <b>Warnings</b> For external use only. <b>Do not use if</b> ■ Seal is damaged ■ Solution changes color or becomes cloudy ■ You are sensitive to any ingredient in this product <b>When using this product</b> ■ Do not touch tip of container to any surface to avoid contamination ■ Replace cap after using ■ Shake off remaining drop before replacing cap <b>Stop use and ask a doctor if</b> ■ 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.	NDC 71776-001-10 <b>FRESHKOTE<sup>®</sup></b> <b>Preservative Free</b> <b>LUBRICANT EYE DROPS</b> <b>The Clear Solution</b> Temporarily Relieves Symptoms of Dry Eye REFER TO FULL SAFETY INFORMATION PRIOR TO USE <b>STERILE</b> 0.33 FL OZ (10 mL) Product of France	<ul style="list-style-type: none"><li>✓ Temporary relief from dry eye</li><li>✓ Gentle, preservative-free drops can be used with contact lenses</li><li>✓ Exclusive patented formulation</li><li>✓ Unique phospholipid blend combats tear evaporation</li><li>✓ State-of-the-art Novelia<sup>®</sup> multidose bottle dispenses drop with precision</li></ul> <b>FRESHKOTE<sup>®</sup></b> Preservative Free is the clear solution for the temporary relief of dry eye symptoms
--	--	---	---



# FRESHKOTE

Preservative Free  
LUBRICANT EYE DROPS

Formulated with preservative-free  
polyethylene glycol for the temporary  
relief of dry eye symptoms

Remove eye contact lens  
and, ensuring vision  
is not affected

In cool, dry, wind  
of the contact lens

Insert 1 or 2 drops in  
the affected eye(s)  
as needed

Obtain one other use.  
Manufactured for  
**Optical Pharmaceuticals**  
For Sale, To Buy  
**FRESHKOTE**  
Product Code

- 1 Temporary relief from dry eye symptoms
- 2 Gentle, preservative-free drops can be used with contact lenses
- 3 Exclusive patented formulation
- 4 Unique polyethylene glycol formula for rapid relief
- 5 Made with the most advanced technology for the most effective eye drop

## Drug Facts

**Active Ingredients** Polyethylene glycol  
**Proprietary** Preservative Free

**Uses**  
For the temporary relief of dry eye symptoms associated with contact lens use

**Warnings**  
Do not use if you have a known hypersensitivity to any of the ingredients

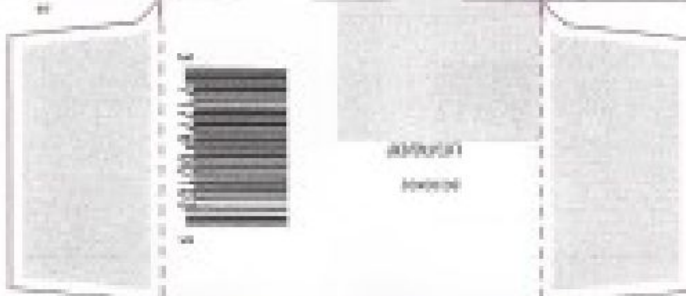
**Directions**  
Insert 1 or 2 drops in the affected eye(s) as needed. Do not use if you have a known hypersensitivity to any of the ingredients. Do not use if you have a known hypersensitivity to any of the ingredients. Do not use if you have a known hypersensitivity to any of the ingredients.

**Other information**  
Contains polyethylene glycol. Do not use if you have a known hypersensitivity to any of the ingredients.

**Contains**  
Polyethylene glycol


**Contains**  
Polyethylene glycol

**Contains**  
Polyethylene glycol



Temporary relief from dry eye symptoms  
Preservative Free  
LUBRICANT EYE DROPS  
FRESHKOTE

Temporary relief from dry eye symptoms  
Preservative Free  
LUBRICANT EYE DROPS  
FRESHKOTE

LOT/EXP. DIRECTIONS: Instill 1 or 2 drop(s)  
 in the affected eye(s) as needed.  
 WARNINGS:  
**FOR EXTERNAL USE ONLY.**  
 See carton for full safety information.  
 ACTIVE INGREDIENTS:  
 Polyvinyl alcohol 2.7%, Povidone 2.0%.  
 STORAGE: Store at 20-25°C (68-77°F).  
**DO NOT USE IF SEAL IS DAMAGED.**  
 Eyevance Pharmaceuticals, LLC  
 Fort Worth, TX 76102  
 1-844-750-1159



22377401

## FRESHKOTE PRESERVATIVE FREE LUBRICANT EYE DROPS

povidone, polyvinyl alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71776-001
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

<b>POVIDONE</b> (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	20 g in 1000 mL
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990) (POLYVINYL ALCOHOL, UNSPECIFIED - UNII:532B59J990)	POLYVINYL ALCOHOL, UNSPECIFIED	27 g in 1000 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>EGG PHOSPHOLIPIDS</b> (UNII: 1Z74184RGV)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71776-001-10	1 in 1 BOX	03/13/2019	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:71776-001-03	30 in 1 BOX	12/06/2020	
2		0.3 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M018	03/13/2019	

**Labeler** - Eyevance Pharmaceuticals (080876046)

### Establishment

Name	Address	ID/FEI	Business Operations
ExcelVision		274234566	manufacture(71776-001) , pack(71776-001)

Revised: 10/2023

Eyevance Pharmaceuticals