## ARTIFICAL TEARS- polyvinyl alcohol, and povidone solution/ drops medsource pharmaceuticals

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.

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#### Active ingredients Purpose

Polyvinyl alcohol 0.5%.....Lubricant

Povidone 0.6%.....Lubricant

#### Uses

- For the temporary relief of burning & irritation due to dryness of the eye
- For use as a protectant against further irritation or to relieve dryness of the eye

#### **Warnings**

For external use only.

#### Do not use

• if solution changes color or becomes cloudy.

#### When using this product

- to avoid contamination, do not touch tip to any surface
- 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 of the eye
- the condition worsens
- symptoms last for 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 drops in the affected eye(s) as needed.
- store at room temperature
- remove contact lenses before using

#### **Inactive ingredients**

benzlkonium chloride, dibasic sodium phosphate hydrate, edetate disodium, glucose, hydrochloric acid, monobasic sodium phosphate, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate hydrate, sodium hydroxide

#### Distributed by:

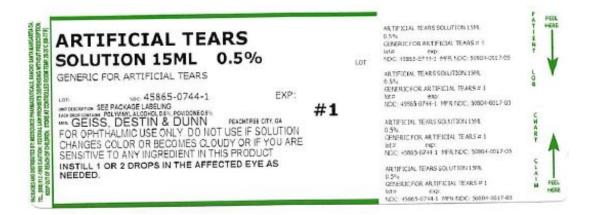
Geiss, Destin & Dunn, Inc.

Peachtree, City, GA 30269

www.valuelabels.com

1-866-696-0957

Made in Korea



#### ARTIFICAL TEARS

polyvinyl alcohol, and povidone solution/ drops

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:45865-744(NDC:50804-017)

Route of Administration OPHTHALMIC

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength POLYVINYL ALCOHOL (UNII: 532B59J990) (POLYVINYL ALCOHOL - UNII:532B59J990) POLYVINYL ALCOHOL 0.05 g in 1 mL POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E) POVIDONE 0.06 g in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
SODIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)				
EDETATE DISO DIUM (UNII: 7FLD91C86K)				
HYDRO CHLO RIC ACID (UNII: QTT17582CB)				
SODIUM PHO SPHATE, MO NO BASIC, DIHYDRATE (UNII: 5QWK665956)				
POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)				
WATER (UNII: 059QF0KO0R)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM HYDRO XIDE (UNII: 55X04QC32I)				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:45865-744- 01	1 in 1 PACKAGE	06/01/2018		
1		15 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	04/04/2016				

### Labeler - medsource pharmaceuticals (833685915)

Establishment						
Name	Address	ID/FEI	Business Operations			
medsource pharmaceuticals		833685915	repack(45865-744)			

Revised: 12/2018 medsource pharmaceuticals