

## **ARTIFICIAL TEARS- artificial tears solution/ drops**

### **AvPAK**

*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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### **Artificial Tears Ophthalmic Solution**

<b>Active ingredients</b>	<b>Purpose</b>
Dextran 70 0.1%	Lubricant
Glycerin 0.2%	Lubricant
Hypromellose 0.3%	Lubricant

### **Uses**

- For the temporary relief of burning, irritation and discomfort due to dryness of the eye or exposure to wind or sun
- May be used as a protectant against further irritation

### **Warnings**

#### **For use in the eyes only**

#### **Do not use**

- if this solution changes color or becomes cloudy

#### **When using this product**

- Avoid contamination, do not touch tip of container to any surface
- Replace cap after use

#### **Stop use and ask a doctor if** you experience any of the following:

- You experience eye pain, changes in vision, continued redness and irritation of the eye
- The condition worsens or persists for more than 72 hours

#### **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

## Directions

- Shake well before use
- Instill 1 or 2 drops in the affected eye(s) as needed

## Other Information

- store at room temperature

## Inactive ingredients:

benzalkonium chloride, boric acid, calcium chloride, glycine, hydrochloric acid and/or sodium hydroxide (to adjust pH), magnesium chloride, polysorbate 80, potassium chloride, purified water, sodium chloride, zinc chloride.

## Questions?

1-855-361-3993


Distributed by:  
AvKARE

Pulaski, TN 38478

www.avkare.com

Rev. 12/2022 AV 12/2022

## PRINCIPAL DISPLAY PANEL



**NDC 50268-043-15**

**Artificial Tears**  
**Ophthalmic Solution**

Dextran 70 0.1% / Glycerin 0.2% /  
Hypromellose 0.3%  
(Eye Lubricants)

**Lubricant Eye Drops**  
**STERILE**  
**0.5 FL OZ (15 mL)**

**DO NOT USE IF TAMPER EVIDENT SEAL IS TORN, BROKEN OR MISSING**

**Drug Facts**

**Active ingredient**.....**Purpose**  
Dextran 70 0.1%, Glycerin 0.2%  
Hypromellose 0.3%.....Eye Lubricant

**Use:** • For the temporary relief of burning, irritation and discomfort due to dryness of the eye or exposure to wind or sun. May be used as a protectant against further irritation.

**Warnings:** For use in the eyes only  
**Keep this and all drugs out of the reach of children.**

**Directions:** Instill 1 or 2 drops in the affected eye(s) as needed.

**Other information:** **DO NOT USE IF IMPRINTED SEAL ON CAP IS TORN, BROKEN OR MISSING.**  
• Retain outer carton for full product information.

**Inactive ingredients:** See outer carton.  
**Questions? 1-855-361-3993**

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Rev. 12/2022 AV 12/2022

## ARTIFICIAL TEARS

artificial tears solution/ drops

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:50268-043
Route of Administration		OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>DEXTRAN 70</b> (UNII: 7SA290YK68) (DEXTRAN 70 - UNII:7SA290YK68)	DEXTRAN 70	1 mg in 1 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	2 mg in 1 mL
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO) (HYPROMELLOSES - UNII:3NXW29V3WO)	HYPROMELLOSES	3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
<b>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>CALCIUM CHLORIDE</b> (UNII: M4I0D6VV5M)	
<b>GLYCINE</b> (UNII: TE7660XO1C)	
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B)	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-043-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	01/05/2023	

**Labeler -** AvPAK (832926666)