

**ARTIFICIAL TEARS- polyvinyl alcohol, unspecified solution/ drops  
Akorn**

*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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**Drug Facts**

**Active ingredient**

Polyvinyl Alcohol 1.4%

**Purpose**

Eye lubricant

**Uses**

For use as a lubricant to prevent further irritation or to relieve dryness of the eye(s).

**Warnings**

- **Do not use if imprinted seal on the bottle neck is broken or missing.**
- **Do not use if solution changes color or becomes cloudy.**
- **To avoid contamination, do not touch tip of container to any surface.**
- **Replace cap after using.**

**Stop use and ask a doctor if**

you experience eye pain, changes in vision, continued redness or irritation of the eye, or if 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.

**Directions**

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

**Other information**

- **Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].**
- **Store away from heat.**
- **Protect from freezing.**
- **Keep tightly closed. RETAIN THIS CARTON FOR FUTURE REFERENCE.**

## Inactive ingredients

Benzalkonium Chloride 0.005% (preservative), Edetate Disodium, Sodium Chloride, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Water for Injection, Sodium Hydroxide and/or Hydrochloric Acid to adjust pH.

## Questions?

call toll-free 1-800-932-5676, weekdays, 7:00 AM - 5:30 PM CST

Principal Display Panel Text for Container Label:

NDC 17478-060-12

Artificial

Tears

Solution

Polyvinyl

Alcohol 1.4%

Lubricant

Eye Drops

Sterile

15 mL (0.5 fl. oz.)

0344



NJATAKL Rev. 08/16

**NDC 17478-060-12**

**Artificial  
Tears  
Solution**

**Polyvinyl  
Alcohol 1.4%**

**Lubricant  
Eye Drops**

**Sterile  
15 mL (0.5 fl. oz.)**

**Each mL contains:**  
**Active:** Polyvinyl Alcohol 1.4%  
**Directions:** Instill 1 or 2 drops in the affected eye(s) as needed.  
**Uses:** For use as a lubricant to prevent further irritation or to relieve dryness of the eye(s).  
**Warnings:** **DO NOT USE IF IMPRINTED SEAL IS MISSING OR BROKEN.** Do not use if solution changes color or becomes cloudy. To avoid contamination, do not touch tip of container to any surface. Replace cap after using. If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a physician.  
**Storage:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Store away from heat, protect from freezing, keep tightly closed.  
**FOR USE IN THE EYE(S) ONLY. KEEP OUT OF REACH OF CHILDREN.** If swallowed, get medical help or contact a Poison Control Center right away.

**AKORN** Mfd. by: **Akorn, Inc.**  
Lake Forest, IL 60045 [www.akorn.com](http://www.akorn.com)



(01)00317478060123

Principal Display Panel Text for Carton Label:

NDC 17478-060-12

15 mL

Artificial

Tears

Solution

Polyvinyl Alcohol 1.4%

Lubricant Eye Drops

Prevents Irritation and Relieves

Dryness of the Eye

Sterile

15 mL (0.5 fl. oz.)



003305

NDC 17478-060-12

FOR OPHTHALMIC  
USE ONLY

**Drug Facts**  
(continued)

**Other information**

- Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
  - Store away from heat.
  - Protect from freezing.
  - Keep tightly closed.
- RETAIN THIS CARTON FOR FUTURE REFERENCE.

**Inactive ingredients**

Benzalkonium Chloride 0.005% (preservative), Edetate Disodium, Sodium Chloride, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Water for Injection USP, Sodium Hydroxide and/or Hydrochloric Acid to adjust pH.

**Questions?**

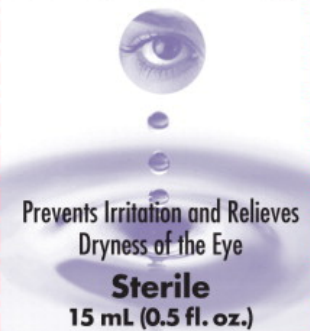
call toll-free 1-800-932-5676, weekdays, 7:00 AM - 5:30 PM CST

NJATAKC Rev 08/16

15 mL

**Artificial Tears Solution**

Polyvinyl Alcohol 1.4%  
Lubricant Eye Drops



N 3 17478-060-12 3

**AKORN**

Manufactured by:  
**Akorn, Inc.**  
Lake Forest IL 60045  
www.akorn.com

**Drug Facts**

Active ingredient	Purpose
Polyvinyl Alcohol 1.4%	Eye lubricant

**Uses**

For use as a lubricant to prevent further irritation or to relieve dryness of the eye(s).

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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. ▶

**ARTIFICIAL TEARS**

polyvinyl alcohol, unspecified solution/ drops

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17478-060
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Polyvinyl Alcohol, Unspecified</b> (UNII: 532B59J990) (Polyvinyl Alcohol,	Polyvinyl Alcohol,	14 mg

Unspecified - UNII:532B59J990)	Unspecified	in 1 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>Benzalkonium Chloride</b> (UNII: F5UM2KM3W7)	
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	
<b>Sodium Phosphate, Dibasic, Anhydrous</b> (UNII: 22ADO53M6F)	
<b>Sodium Phosphate, Monobasic, Anhydrous</b> (UNII: KH7I04HPUU)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Hydrochloric Acid</b> (UNII: QTT17582CB)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-060-12	1 in 1 CARTON	03/01/1998	
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	03/01/1998	

**Labeler** - Akorn (117696770)

**Registrant** - Akorn Operating Company LLC (117693100)

### Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(17478-060) , ANALYSIS(17478-060) , STERILIZE(17478-060) , PACK(17478-060) , LABEL(17478-060)

Revised: 1/2022

Akorn