ARTIFICIAL TEARS- polyvinyl alcohol solution/ drops
MWI

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.

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.

Principal Display Panel Text for Container Label:

NDC 13985-601-15

Artificial Tears

Solution

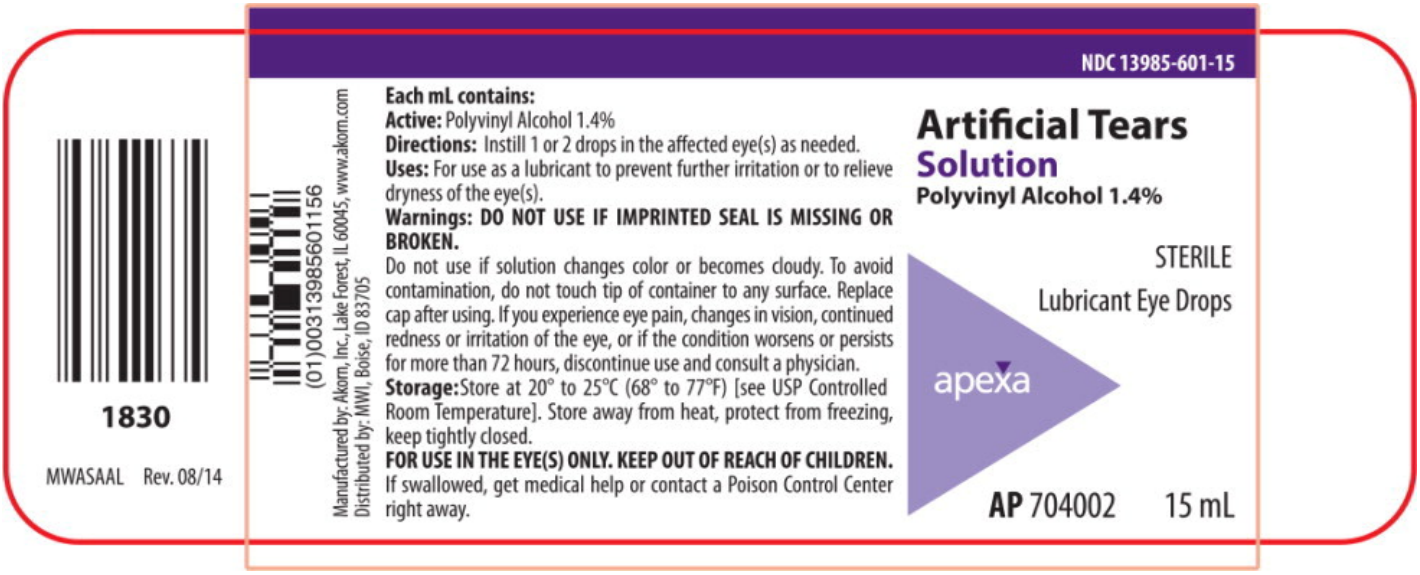
Polyvinyl Alcohol 1.4%

STERILE

Lubricant Eye Drops

Apexa logo

AP 704002 15 mL



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Prevents Irritation

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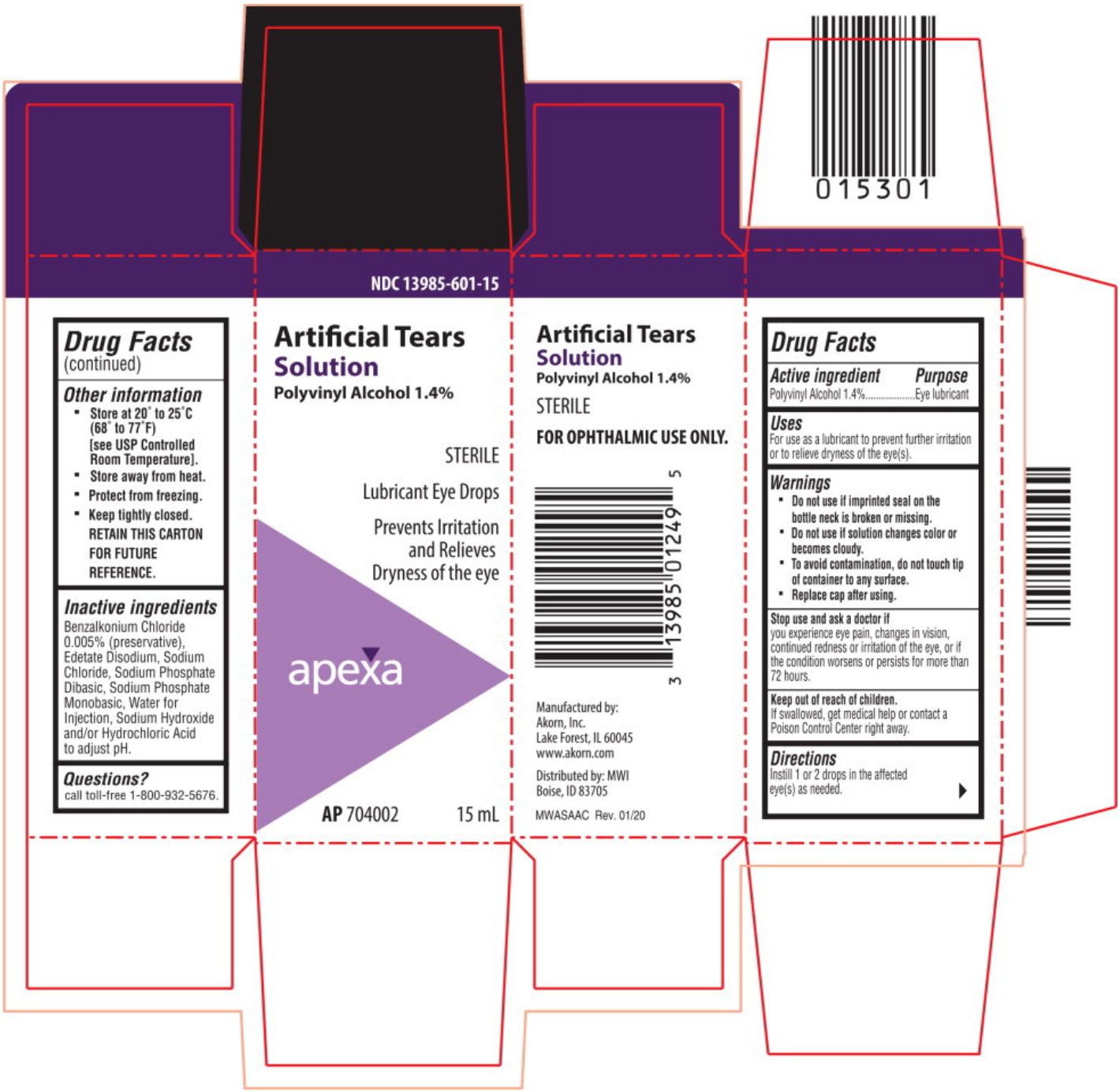

ARTIFICIAL TEARS

polyvinyl alcohol solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13985-601
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	14 mg in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13985-601-15	1 in 1 CARTON	03/23/2015	
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	03/23/2015	

Labeler - MWI (019926120)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(13985-601) , ANALYSIS(13985-601) , STERILIZE(13985-601) , PACK(13985-601) , LABEL(13985-601)