

ARTIFICIAL TEARS- polyvinyl alcohol solution/ drops

Akorn

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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

condition persists or increases discontinue use and consult a veterinarian.

Keep out of the 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 USP, 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 59399-160-15

15 mL

ARTIFICIAL

TEARS

SOLUTION

Polyvinyl Alcohol 1.4%

Lubricant Eye Drops

For Veterinary Use

Sterile

15 mL (0.5 fl. oz.)



The image shows a rectangular label with rounded corners, outlined in red. On the left side, there is a barcode with the number 1272 below it. Below the barcode, the text reads "ATAVL Rev. 10/19". The main body of the label contains the following text: "NDC 59399-160-15" at the top left. Below this, "15 mL" is written in white on a red oval background. The product name "ARTIFICIAL TEARS SOLUTION" is written in large, bold, orange letters. Below the product name, "Polyvinyl Alcohol 1.4%" is written in a smaller font. The text "Lubricant Eye Drops" and "For Veterinary Use" follows. At the bottom left, it says "Sterile 15 mL (0.5 fl. oz.)". On the right side, there is a section titled "Each mL contains:" followed by "Active: Polyvinyl Alcohol 1.4%". Below that, "Directions: Instill 1 or 2 drops in the affected eye(s) as needed." and "Uses: For use as a lubricant to prevent further irritation or to relieve dryness of the eye(s)." are listed. A warning section states "Warnings: DO NOT USE IF IMPRINTED SEAL IS MISSING OR BROKEN." and provides instructions on what to do if the solution changes color or becomes cloudy. Storage instructions are given as "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." A bolded statement reads "FOR USE IN THE EYE(S) ONLY. KEEP OUT OF THE REACH OF CHILDREN." followed by "If swallowed, get medical help or contact a Poison Control Center right away." At the bottom right, the Akorn Animal Health logo is present, along with the text "Mfd by: Akorn, Inc., Lake Forest, IL 60045 www.akorn.com". To the right of the logo is a barcode with the number "(01)00359399160155" below it.

Principal Display Panel Text for Carton Label:

NDC 59399-160-15

Akorn Animal Health Logo

15 mL

ARTIFICIAL

TEARS

SOLUTION

Polyvinyl Alcohol 1.4%

Lubricant Eye Drops

For Veterinary Use

Prevents Irritation and

Relieves Dryness

of the Eye

Sterile

15 mL (0.5 fl. oz.)



ARTIFICIAL TEARS

polyvinyl alcohol solution/ drops

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:59399-160
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

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

Unspecified - UNII:532B59J990)	Unspecified	in 1 mL
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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:59399-160-15	1 in 1 CARTON		
1		15 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/15/2015	

Labeler - Akorn (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE, ANALYSIS, STERILIZE, PACK, LABEL

Establishment

Name	Address	ID/FEI	Business Operations
Avantor Performance Materials International, Inc.		152791026	API MANUFACTURE

Revised: 11/2022

Akorn