ARTIFICIAL TEARS- mineral oil and petrolatum ointment 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 ingredients

Mineral Oil 15%

White Petrolatum 83%

Purpose

Eye lubricant

Eye lubricant

Uses

For use as a lubricant to prevent further irritation or to relieve dryness of the eyes.

Warnings

- For external use only.
- 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 the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Pull down lower lid of the affected eye(s) and apply small amount (one-fourth inch) of ointment to the inside of the eyelid, one or more times daily, or as directed by a doctor.

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.
- See crimp for Control Number and Expiration Date.
- RETAIN THIS CARTON FOR FUTURE REFERENCE.

Inactive ingredient

Lanolin 2%

Principal Display Panel Text for Container Label:

NDC 13985-600-03

Apexa logo

Artificial Tears STERILE

Ophthalmic Lubricant Ointment

Prevents Irritation and Relieves Dryness of the eye

Can be used at bedtime

AP 704001 Net Weight: 3.5g (1/8 oz)



Principal Display Panel Text for Carton Label:

NDC 13985-600-03

Artificial Tears

Ophthalmic

Lubricant

Ointment

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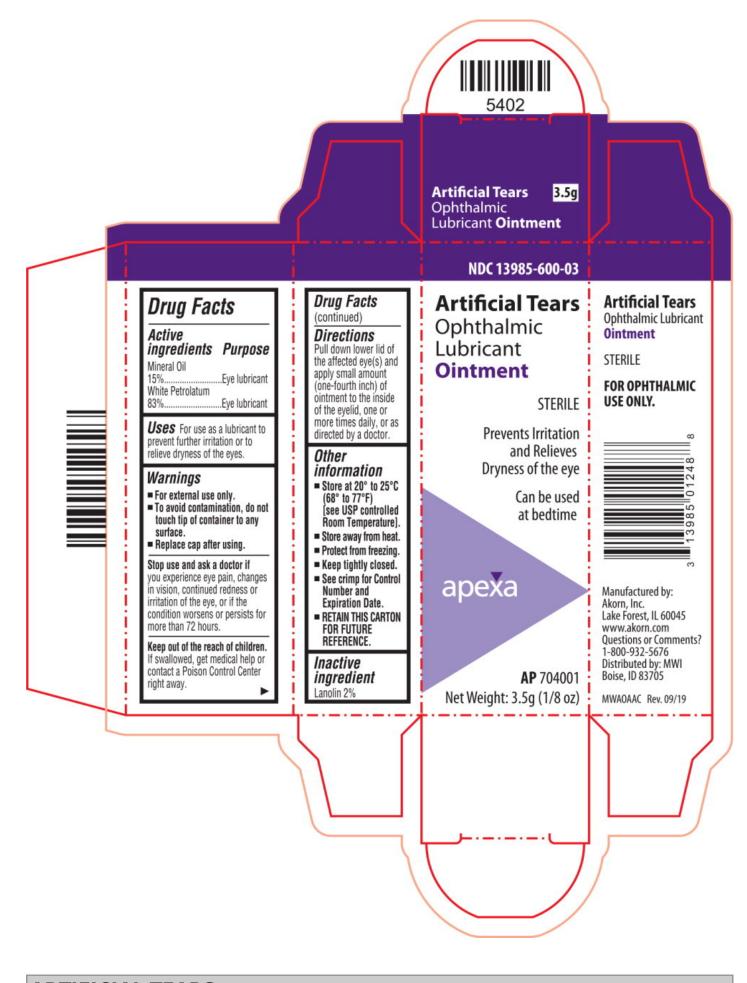
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Apexa logo

AP 704001

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mineral oil and petrolatum ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:13985-600

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety

7.00.1.0 mg. 00.10.1.47 to 1.10.10.19			
Ingredient Name	Basis of Strength	Strength	
Mineral Oil (UNII: T5L8T28FGP) (Mineral Oil - UNII:T5L8T28FGP)	Mineral Oil	150 mg in 1 g	
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	830 mg in 1 g	

Inactive Ingredients

Ingredient Name Strength

Lanolin (UNII: 7EV65EAW6H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:13985-600- 03	1 in 1 CARTON	03/23/2015		
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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(13985-600), ANALYSIS(13985-600), STERILIZE(13985-600), PACK(13985-600), LABEL(13985-600)	

Revised: 2/2022 MWI