

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)

NDC 13985-600-03



Artificial Tears

STERILE

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FOR OPHTHALMIC USE ONLY

READ OUTER CARTON FOR INFORMATION BEFORE USING.

Active ingredients: Mineral Oil 15%, and White Petrolatum 83%.

Inactive ingredient: Lanolin 2%.

Indications: For use as a lubricant to prevent further irritation or relieve dryness of the eyes. **Directions:** Pull down the lower lid of the affected eye(s) and apply a small amount (one-fourth inch) of ointment to the inside of the eyelid, one or more times daily, or as directed by a doctor. See crimp of tube for Control No. and Exp. Date.

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. **KEEP TIGHTLY CLOSED.**

Warning: KEEP OUT OF THE REACH OF CHILDREN.

DO NOT USE IF BOTTOM RIDGE OF TUBE CAP IS EXPOSED.

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

Distributed by: MWI
Boise, ID 83705
MWAOAAL Rev. 07/14



(01) 00313985600036

LT-2448

Principal Display Panel Text for Carton Label:

NDC 13985-600-03

Artificial Tears

Ophthalmic

Lubricant

Ointment

STERILE

Prevents Irritation

and Relieves

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AP 704001

Net Weight: 3.5g (1/8 oz)



5402

Artificial Tears **3.5g**
Ophthalmic
Lubricant **Ointment**

NDC 13985-600-03

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15%.....Eye lubricant
White Petrolatum
83%.....Eye lubricant

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Drug Facts

(continued)

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apexa

AP 704001

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Artificial Tears
Ophthalmic Lubricant
Ointment

STERILE

**FOR OPHTHALMIC
USE ONLY.**



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Manufactured by:
Akorn, Inc.
Lake Forest, IL 60045
www.akorn.com
Questions or Comments?
1-800-932-5676
Distributed by: MWI
Boise, ID 83705

MWAOAAC Rev. 09/19

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

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 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(13985-600) , ANALYSIS(13985-600) , STERILIZE(13985-600) , PACK(13985-600) , LABEL(13985-600)

Revised: 2/2022

MW