

## **ARTIFICIAL TEARS- mineral oil and petrolatum ointment**

### **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**

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 17478-062-35 Akorn Logo

Artificial Tears OINTMENT

Lubricant Eye Ointment

Sterile

FOR OPHTHALMIC USE ONLY Net Wt. 3.5 g (1/8oz.)

<b>NDC 17478-062-35</b>			
<b>Artificial Tears</b>		<b>OINTMENT</b>	
Lubricant Eye Ointment		<b>Sterile</b>	
FOR OPHTHALMIC USE ONLY		<b>Net Wt. 3.5 g (1/8 oz.)</b>	
<b>READ OUTER CARTON FOR INFORMATION BEFORE USING.</b>			
<b>Active ingredients:</b> Mineral Oil 15%, and White Petrolatum 83%. <b>Inactive ingredient:</b> Lanolin 2%. <b>INDICATIONS:</b> For use as a lubricant to prevent further irritation or relieve dryness of the eyes. <b>DIRECTIONS:</b> 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.			
<b>STORAGE:</b> Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. <b>KEEP TIGHTLY CLOSED.</b>			
<b>WARNING: KEEP OUT OF THE REACH OF CHILDREN.</b>			
<b>DO NOT USE IF BOTTOM RIDGE OF TUBE CAP IS EXPOSED.</b>			
Manufactured by: <b>Akorn, Inc.</b> , Lake Forest, IL 60045 <a href="http://www.akorn.com">www.akorn.com</a> NJAKAAL Rev. 10/13		 (01) 00317478062356	
		LT-2449-6	

Principal Display Panel Text for Carton Label:

NDC 17478-062-35

3.5 g

Artificial

Tears

OINTMENT

Lubricant

Eye Ointment

Can Be Used at Bedtime

Sterile

Net Wt. 3.5 g (1/8oz.)



0506

# Artificial Tears

OINTMENT **3.5 g**

NDC 17478-062-35

FOR OPHTHALMIC  
USE ONLY

Questions  
1-800-932-5676

**3.5 g**

# Artificial Tears

OINTMENT

Lubricant  
Eye Ointment



Can Be Used at Bedtime

**Sterile**  
Net Wt. 3.5 g (1/8 oz.)



 **AKORN**

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

## Drug Facts

### Active ingredients Purpose

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

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## Drug Facts

(continued)

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### Inactive ingredient

Lanolin 2%

NJAKAAC Rev. 10/13



mineral oil and petrolatum ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17478-062
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Mineral Oil</b> (UNII: T5L8T28FGP) (Mineral Oil - UNII:T5L8T28FGP)	Mineral Oil	150 mg in 1 g
<b>Petrolatum</b> (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	830 mg in 1 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>Lanolin</b> (UNII: 7EV65EAW6H)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:17478-062-35	1 in 1 CARTON	09/01/1990	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part349	09/01/1990	

**Labeler** - Akorn (117696770)

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

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Akorn		117696840	MANUFACTURE(17478-062) , ANALYSIS(17478-062) , STERILIZE(17478-062) , PACK(17478-062) , LABEL(17478-062)

Revised: 1/2022

Akorn