

LUBRICANT EYE- mineral oil and petrolatum ointment

Akorn, Inc.

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

Mineral Oil

12%

White Petrolatum

88%

Contains no preservatives or lanolin.

Purpose

Eye lubricant

Eye lubricant

Uses

For use as a lubricant for the temporary relief of burning and irritation due to dryness of the eyes.

Warnings

- **Do not use if bottom ridge of tube is exposed.**
- **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.**

NJTROAC Rev. 06/12


Principal Display Panel Text for Container Label:

NDC 17478-063-35 Akorn Logo

Lubricant Eye OINTMENT

Nighttime Relief For Dry Eyes Sterile

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

NDC 17478-063-35 

Lubricant Eye OINTMENT

Nighttime Relief for Dry Eyes **Sterile**

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

READ OUTER CARTON FOR INFORMATION BEFORE USING.

Active ingredient: Mineral Oil 12%, White Petrolatum 88%.
Contains no preservatives or lanolin.


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. **Uses:** For use as a lubricant for the temporary relief of burning and irritation due to dryness of the eyes. See crimp of tube for Control Number and Expiration 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 NJTROAL Rev. 06/12 (01) 00317478063353

LT-0819-5 

Principal Display Panel Text for Carton Label:

NDC 17478-063-35

3.5 g

Lubricant

Eye

OINTMENT

Nighttime Relief

For Dry Eyes

Nighttime Relief

Plus Protection

Sterile

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



0705

Drug Facts

Active ingredient Purpose

Mineral Oil
12%.....Eye lubricant
White Petrolatum
88%.....Eye lubricant
Contains no preservatives or lanolin.

Uses For use as a lubricant for the temporary relief of burning and irritation due to dryness of the eyes.

Warnings

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- To avoid contamination, do not touch tip of container to any surface.
- Replace cap after using.

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Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away. ▶

Drug Facts

(continued)

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.

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NDC 17478-063-35

FOR OPHTHALMIC USE ONLY

3.5 g

Lubricant Eye OINTMENT

Nighttime Relief for Dry Eyes



Nighttime Relief Plus Protection

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

Questions
1-800-932-5676



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AKORN

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

NJTROAC Rev. 06/12

mineral oil and petrolatum ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:17478-063 |
| Route of Administration | OPHTHALMIC | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| Mineral Oil (UNII: T5L8T28FGP) (Mineral Oil - UNII:T5L8T28FGP) | Mineral Oil | 120 mg in 1 g |
| Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U) | Petrolatum | 880 mg in 1 g |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:17478-063-35 | 1 in 1 CARTON | | |
| 1 | | 3.5 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part349 | 04/01/1993 | |

Labeler - Akorn, Inc. (062649876)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------|---------|-----------|--|
| Akorn, Inc | | 603980319 | MANUFACTURE(17478-063) , ANALYSIS(17478-063) , STERILIZE(17478-063) , PACK(17478-063) , LABEL(17478-063) |

Revised: 10/2012

Akorn, Inc.