

**LUBRICANT PM- mineral oil, white petrolatum lubricant eye ointment ointment
AACE PHARMACEUTICALS, 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.

SPL UNCLASSIFIED SECTION

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ACTIVE INGREDIENTS

Mineral Oil 42.5% and White Petrolatum 57.3%

PURPOSE

Lubricant

USES

- For the temporary relief of burning, irritation and discomfort due to dryness of the eye or exposure to wind and sun.
- May be used as a protectant against further irritation.

WARNINGS

- For external use only.
- To avoid contamination, do not touch the tip of container to any surface. Replace cap after using.

Stop use and ask a doctor if

- you feel eye pain.
- changes in vision occur.
- redness or irritation of the eye(s) gets worse, persists or lasts more than 72 hours.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

- Pull down the lower lid of the affected eye and apply a small amount (one fourth inch) of ointment to the inside of the eyelid.

OTHER INFORMATION

- Store away from heat.

- Protect from freezing.
- Use only if tape seals on top and bottom flaps are intact.
- Use before expiration date marked on container.
- Store at 15° to 30°C (59° to 86°F).

RETAIN THIS CARTON FOR FUTURE REFERENCE.

INACTIVE INGREDIENTS

Lanolin Alcohols.

PRINCIPAL DISPLAY PANEL

NDC#: 71406-124-35

Compare to Refresh P.M.® Ointment active ingredients*

Lubricant PM Ointment

Sensitive

Preservative Free

Ointment for Nighttime Dry Eye Relief

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




Distributed By:

AACE Pharmaceuticals, Inc., Fairfield, NJ 07004

www.aacepharma.com

Rev. 00

*This product is not manufactured by Allergan, Inc. distributor of Refresh PM® Ointment.

							
<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> ■ Pull down the lower lid of the affected eye and apply a small amount (one fourth inch) of ointment to the inside of the eyelid. <p>Other Information</p> <ul style="list-style-type: none"> ■ Store away from heat. ■ Protect from freezing. ■ Use only if tape seals on top and bottom flaps are intact. ■ Use before expiration date marked on container. ■ Store at 15° to 30°C (59° to 86°F). <p>RETAIN THIS CARTON FOR FUTURE REFERENCE.</p> <p>Inactive Ingredients Lanolin Alcohols.</p>	 <p>NDC#: 71406-124-35</p> <p>Compare to Refresh P.M.® Ointment active ingredients*</p> <p>Lubricant PM Ointment</p> <p>Sensitive Preservative Free</p> <p>Ointment for Nighttime Dry Eye Relief</p> <p>Net Wt. 3.5 g (1/8 oz) Sterile</p>	<p>Lubricant PM Ointment <i>provides strong, soothing nighttime relief for more intense dry, irritated eyes. Ideal for use at bedtime.</i></p> <p>*This product is not manufactured by Allergan, Inc., distributor of Refresh PM® Ointment.</p>  <p>Distributed by : AACE Pharmaceuticals, Inc., Fairfield, NJ 07004 www.aacepharma.com Rev. 00</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Mineral Oil 42.5% and.....Lubricant White Petrolatum 57.3%</td> <td></td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> ■ For the temporary relief of burning, irritation and discomfort due to dryness of the eye or exposure to wind and sun. ■ May be used as a protectant against further irritation. <p>Warnings</p> <ul style="list-style-type: none"> ■ For external use only. ■ To avoid contamination, do not touch the tip of container to any surface. Replace cap after using. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ you feel eye pain ■ changes in vision occur ■ redness or irritation of the eye(s) gets worse, persists or lasts more than 72 hours. <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	Active Ingredients	Purpose	Mineral Oil 42.5% and.....Lubricant White Petrolatum 57.3%	
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	<p>Lot #:</p> <p>Exp. Date:</p>						

LUBRICANT PM
mineral oil, white petrolatum lubricant eye ointment ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71406-124
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	425 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	573 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71406-124-35	1 in 1 CARTON	03/19/2020	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		



Drug Facts
(continued)

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Ointment for Nighttime
Dry Eye Relief

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provides strong, soothing nighttime relief for more intense dry, irritated eyes. Ideal for use at bedtime.

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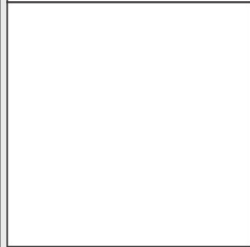
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Lot #:
Exp. Date:



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	03/19/2020	

