PURALUBE- light mineral oil, white petrolatum ointment
Paddock Laboratories, LLC

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.

Puralube® Ointment Drug Facts

Active ingredients

Light Mineral Oil 15%

White Petrolatum 85%

Purpose

Eye Lubricant

Uses

- as a lubricant to prevent further irritation of the eye
- to relieve dryness of the eye(s).

Warnings

For external use only

When using this product

- 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
- the condition worsens or persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

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

Other information

- store at 20°- 25°C (68°- 77°F)

- protect from freezing
- see crimp of tube or box for lot number and expiration date.
- keep tightly closed.
- Save box for complete information.

Questions or comments?

Call 1-800-719-9260

Consumer information

PURALUBE® OINTMENT

PETROLATUM OPHTHALMIC OINTMENT

STERILE

OCULAR LUBRICANT

DESCRIPTION: a sterile ocular emollient (lubricant).

Active ingredients

Light mineral oil 15%

White petrolatum 85%

Purposes

Eye lubricant

Uses: for use as a lubricant to prevent further irritation or to relieve dryness of the eye.

Warnings:

For external use only

When using this product:

- To avoid contamination of this product do not touch the tip of the container to any surface.
- For the multi-use container: Replace the cap after using.
- For the single-use container: Do not reuse. Once opened, discard.

Stop using and ask a doctor if:

- You experience eye pain.
- Changes in vision.
- Continued redness or irritation of the eye.
- The condition worsens or persists for more than 72 hours.

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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

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

See crimp of tube or box for lot number and expiration date.

Store at 20 to 25°C (68 to 77°F)

KEEP TIGHTLY CLOSED

HOW SUPPLIED:

1/8 OZ (3.5 g) Tube (multi-use container) NDC 0574-**4025**-35

Carton of Twenty (20) Unit Dose 1 g Tube (single-use container) NDC 0574-**4025**-20

Manufactured for Perrigo, Minneapolis, MN 55427

Questions or comments? Call **1-800-719-9260**

Rev 04-14 A

6Y000 RT J1

R0414

Ini 0414

Package/Label Principal Display Panel

Nighttime Relief

Puralube® Ointment

preservative free

prevent further irritation

relieves dryness

Petrolatum Ophthalmic Ointment

Sterile Ocular Lubricant

NET WT 3.5 g (1/8 oz)

NDC 0574-**4025**-35

Nighttime Relief

Puralube® Ointment

- preservative free
- prevent further irritation
- relieves dryness

Petrolatum Ophthalmic Ointment
Sterile Ocular Lubricant

Actual Size

FPO

Void Area

Puralube® Ointment
Petrolatum Ophthalmic Ointment
Sterile Ocular Lubricant

NET WT 3.5 g (1/8 oz)

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

NDC 0574-**4025**-35

Drug Facts

Active ingredients	Purpose
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White Petrolatum 85%	Eye Lubricant

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Directions ■ pull down lower lid of the affected eye
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Questions or comments? Call 1-800-719-9260

Puralube® Ointment

DO NOT USE IF BOTTOM RIDGE OF TUBE CAP IS EXPOSED AND IMPRINTED CARTON SEAL IS NOT INTACT.

Manufactured for Perrigo, Minneapolis, MN 55427

Rev 10-17 B 6Y021 RT C4

N3 0574-4025-35 8

R0118
Ini 0514

PURALUBE

light mineral oil, white petrolatum ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0574-4025
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIGHT MINERAL OIL (UNII: N6K5787QVP) (LIGHT MINERAL OIL - UNII:N6K5787QVP)	LIGHT MINERAL OIL	150 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	850 mg in 1 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0574-4025-35	1 in 1 CARTON	01/05/2015	01/01/2022
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0574-4025-20	20 in 1 CARTON	07/29/2014	11/01/2020
2	NDC:0574-4025-11	1 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	07/28/2014	01/01/2022

Labeler - Paddock Laboratories, LLC (967694121)

Revised: 4/2019 Paddock Laboratories, LLC