

MINERAL OIL WITH PETROLEUM- mineral oil and white petrolatum ointment **Rugby Laboratories**

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.

Rugby Mineral Oil with Petroleum

Active ingredients	Purpose
Mineral Oil 3%	Lubricant
White Petrolatum 94%	Lubricant

Uses

- For temporary relief of irritation or dryness in the eye.

Warnings

For use in eyes only. Retain outer carton for full product drug facts.

Do not use if: • you are sensitive to any ingredient in this product.

Do not use if bottom ridge of tube is exposed, or if cap of tube is damaged.

Stop use

Stop use and ask a doctor if you are experiencing any of the following:

- You experience eye pain or change in vision, continued dryness or irritation of the eye.
- The condition worsens. • Symptoms last longer 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

• Wash your hands. • Pull down lower lid of the affected eye and apply a small amount (1/4" inch) of ointment to the inside of the eyelid, every 3-4 hours or as directed by doctor.

Other information

- • Do not use if bottom ridge of tube cap is exposed. Store at room temperature 15° to 30° C (59° to 86°F) • Keep tube tightly closed. • See crimp of tube or box for lot number and expiration date.

Inactive ingredient

Lanolin alcohol.

Questions or Comments? • 888-969-6855

PRINCIPAL DISPLAY PANEL

Rugby® NDC 0536-1383-91
Mineral Oil with Petroleum
 3%-94% Ophthalmic Ointment

Rugby® NDC 0536-1383-91
 Compare to the active ingredients in Systane® Nighttime Lubricant Eye Ointment[†]

Mineral Oil with Petroleum
 3%-94% Ophthalmic Ointment

Soothes, Moisturizes & Protects

Sterile
 Preservative Free

0.125 FL OZ (3.5 g)

Drug Facts
Active Ingredients
 Mineral oil 3%
 White petrolatum 94%
Purpose
 Lubricant
 Lubricant

Uses:
 For temporary relief of irritation or dryness in the eye.

Warnings:
 For use in eyes only. Retain outer carton for full product drug facts. Do not use if: • you are sensitive to any ingredient in this product. Stop use and ask a doctor if: • You experience eye pain or change in vision, continued dryness or irritation of the eye. • The condition worsens. • Symptoms last longer than 72 hours. Keep this and all drugs out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1222).

Directions
 • Wash your hands. • Pull down lower lid of the affected eye and apply a small amount (1/4" inch) of ointment to the inside of the eyelid, every 3-4 hours or as directed by doctor.

Other information
 • Do not use if bottom ridge of tube cap is exposed. Store at room temperature 15° to 30° C (59° to 86°F) • Keep tube tightly closed. • See crimp of tube or box for lot number and expiration date.

Inactive ingredients
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Questions or Comments? ☎
 • 888-969-6855

†This product is not manufactured or distributed by Novartis AG Corporation, owner of the registered trademark Systane®.

Distributed by:
RUGBY®
 LABORATORIES
 Indianapolis, IN 46268
 (800) 616-2471
 www.majorpharmaceuticals.com
 Made in Jordan.
 Rev. 01/23
 R-155
 Re-order No. 371142

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Do not use if bottom ridge of tube is exposed, or if cap of tube is damaged.

Save carton for complete drug facts.

ACTUAL SIZE TUBE

Rugby® NDC 0536-1383-91
Mineral Oil with Petroleum
 3%-94% Ophthalmic Ointment

Sterile
 Preservative Free **0.125 FLOZ (3.5 g)**

Drug Facts
Active ingredients Mineral oil 3% White petrolatum 94%
Inactive ingredients Lanolin alcohol

Directions • Refer to outer carton for complete information. • Wash your hands. • Pull down lower lid of the affected eye and apply a small amount (1/4 inch) of ointment to the inside of the eyelid, every 3-4 hours or as directed by doctor.

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 www.majorpharmaceuticals.com Made in Jordan. Rev. 01/23 R-155 Re-order No. 371142
 Questions or Comments? 888-969-6855

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MINERAL OIL WITH PETROLEUM

mineral oil and white petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1383
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	30 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	940 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:0536-1383-91	1 in 1 CARTON	02/27/2023	
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	02/27/2023	

Labeler - Rugby Laboratories (079246066)

Revised: 2/2023

Rugby Laboratories