

DERMACERIN- skin protectant ointment
DermaRite Industries, 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.

DermaCerin

Active Ingredient:

Petrolatum 33%

Purpose:

Skin Protectant

Uses:

- Temporarily protects and helps relieve dry, chapped, or cracked skin.
- Helps protect skin from the drying effects of wind and cold weather.

Warnings:

For external use only.

Avoid contact with eyes. In case of contact, flush thoroughly with water

Warnings:

Stop and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days.

Warnings:

Do not use on deep or puncture wounds, animal bites, or serious wounds.

Warnings:

Keep out of reach of children.

In case of accidental ingestion contact a Physician or Poison Control Center right away.

Directions:

Apply as needed or as directed by a physician.

Other Information:

- Store at room temperature (59°- 86°F)
- You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.

Inactive ingredients:

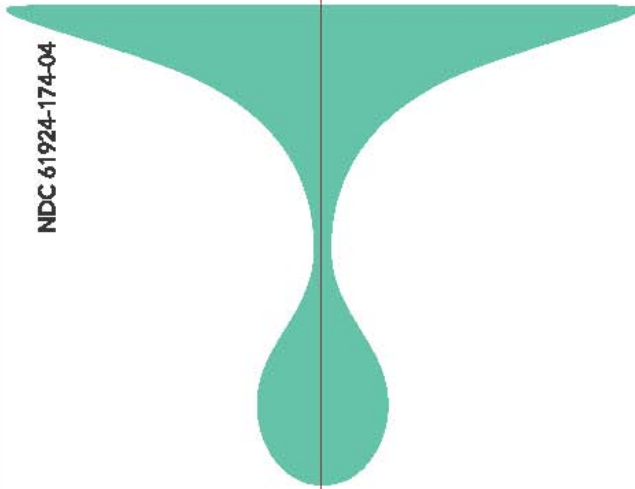
Water, Mineral Oil, Paraffin, Lanolin Alcohol, PEG-30 Dipolhydroxystearate, DMDM Hydantoin, Methylparaben, Propylparaben, Propylene Glycol, Sodium Chloride

Questions?

Call 800-337-6296 Mon - Fri 9AM - 5PM EST.

DermaCerin Package Label and Principal Display Panel

NDC 61924-174-04



DermaCerin™

SKIN PROTECTANT MOISTURIZING CREAM

DermaRite®

REORDER #00174

Net Wt. 106 g (3.75 oz.)

Drug Facts

Active ingredient	Purpose
Petrolatum 33%	Skin protectant

Uses

- Temporarily protects and helps relieve dry, chapped, or cracked skin.
- Helps protect skin from the drying effects of wind and cold weather.

Warnings

For external use only.

Avoid contact with eyes. In case of contact, flush thoroughly with water.

Stop use and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days.

Do not use on deep puncture wounds, animal bites, or serious burns.

Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away.

Directions Apply as needed or as directed by a physician.

Other Information ■ Store at room temperature (59°-86°F) ■ You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.

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Patient Name

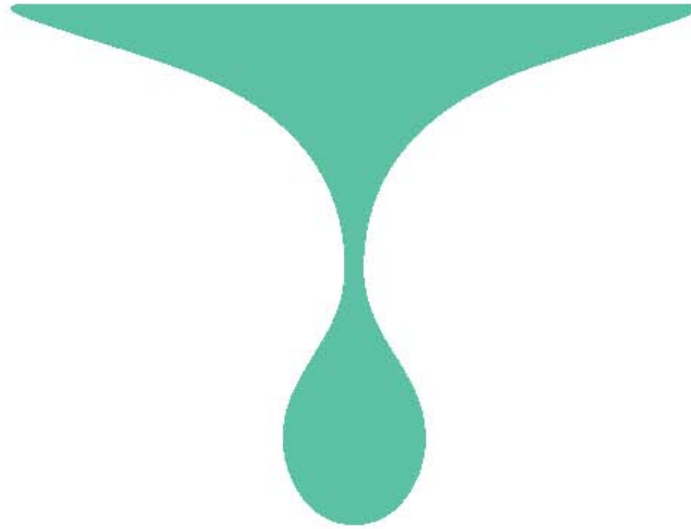
Room #



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DermaRite Industries LLC
7777 West Side Avenue
North Bergen, NJ 07047
www.dermarite.com

**MADE
IN THE
USA**
100832



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SKIN PROTECTANT
MOISTURIZING
CREAM

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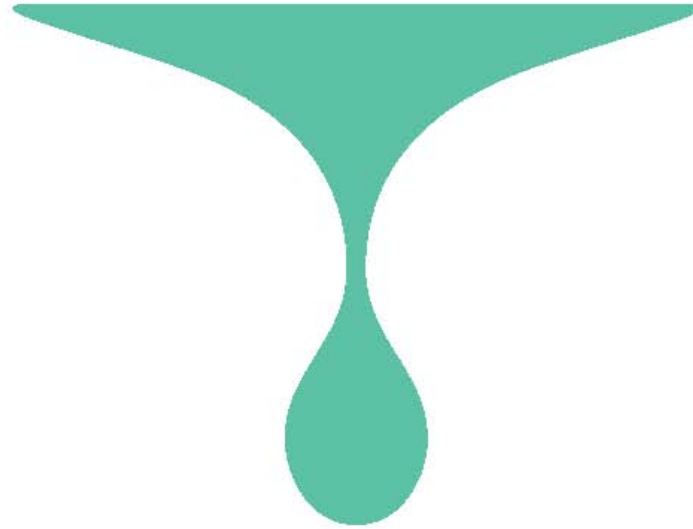
CONTENTS: 24 TUBES - 106g (3.75 oz.) Each



1 0 7 1 4 1 9 6 1 7 4 0 4 5

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DERMACERIN

skin protectant ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61924-174	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)		PETROLATUM	33 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
PARAFFIN (UNII: I9O0E3H2ZE)				
PROPYLENE GLYCOL 2-(2-METHYLBUTYRATE) (UNII: 3Z73C506A9)				
WATER (UNII: 059QF0KO0R)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)				
MINERAL OIL (UNII: T5L8T28FGP)				
DMDM HYDANTOIN (UNII: BYR0546TOW)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-174-04	106 g in 1 TUBE; Type 0: Not a Combination Product	10/17/2016	
2	NDC:61924-174-08	198 g in 1 TUBE; Type 0: Not a Combination Product	10/17/2016	
3	NDC:61924-174-16	454 g in 1 JAR; Type 0: Not a Combination Product	10/17/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	10/17/2016		

Labeler - DermaRite Industries, LLC (883925562)

Registrant - DermaRite Industries, LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
DermaRite Industries, LLC		883925562	manufacture(61924-174)

