DERMAPHOR- 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.

DERMAPHOR

Active Ingredient:

Petrolatum 44.28%

Purpose:

Skin Protectant

Uses:

- Temporarily protects minor cuts, scrapes, burns.
- Temporarily protects and helps relieve chapped or cracked skin and lips.
- Helps protect skin from the drying effects of wind and cold weather.

Warnings:

IFor external use only.

Warnings:

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

Warnings:

Stop and ask a doctor if

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

Warnings:

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

Warnings:

Keep out of reach of children.

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

Directions:

Apply liberally to affected area as needed.

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:

Mineral Oil, Paraffin, Lanolin Alcohol

Questions?:

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

DermaPhor Package Label and Principal Display Panel



Derma**Phor**

SKIN PROTECTANT **MOISTURIZING OINTMENT**

DermaRite^{*}

REORDER #00184

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



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

MADE INTHE USA 100832



Drug Facts Active ingredient Petrolatum 44.28%

PurposeSkin protectant

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

Warnings

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Stop use and ask a doctor if a condition worsens

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

Do not use on deep or 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.

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Other information Store at room temperature (59°-66°F) ■ You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.

Inactive Ingredients

Mineral Oil, Paraffin, Lanclin Alcohol

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Derma**Phor**

SKIN PROTECTANT MOISTURIZING **OINTMENT**

> For dry, cracked, or irritated skin

DermaRite'

REORDER #00184

Net Wt. 106 g (3.75 oz.)

DERMAPHOR

NDC 61924-184-04

skin protectant ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source)

NDC:61924-184

Route of Administration

TOPICAL

Room

101032

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	44 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
MINERAL OIL (UNII: T5L8T28FGP)		
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)		
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)		

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-184-04	106 g in 1 TUBE; Type 0: Not a Combination Product	11/17/2016	
2	NDC:61924-184-08	198 g in 1 TUBE; Type 0: Not a Combination Product	11/17/2016	
3	NDC:61924-184-16	454 g in 1 JAR; Type 0: Not a Combination Product	11/17/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/17/2016	

Labeler - DermaRite Industries, LLC (883925562)

Registrant - DermaRite Industries, LLC (883925562)

Establishment			
Name	Address	ID/FEI	Business Operations
DermaRite Industries, LLC		883925562	manufacture(61924-184)

Revised: 1/2020 DermaRite Industries, LLC