RENEW PERIPROTECT- 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.

Renew Periprotect

Active Ingredients:

Zinc Oxide 12%

Dimethicone 1%

Purpose:

Skin Protectant

Uses:

- Helps treat and prevent diaper rash.
- Protects minor skin irritation associated with

diaper rash and helps seal out wetness.

Warnings:

- For external use only,
- Avoid contact with eyes, In case of contact, flush thoroughly with water.

Warnings:

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.

Warnings:

Keep out of reach of children.

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

Directions:

- Change wet and soiled diapers promptly, cleanse the diaper area and allow to dry.
- Apply cream liberally as often as necessary, with each diaper change, especially at

bedtime or anytime when exposure to wet diapers may be prolonged.

Other Information:

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

Inactive Ingredients:

Aloe Barbadensis Leaf Juice, Aluminum Stearate, Beeswax, Cholecalciferol, Chloroxylenol, Corn Oil, Imidazolidinyl Urea, Fragrance, Lanolin, Methylparaben, Mineral Oil, Paraffin Wax, Petrolatum, Phenoxyethanol, Propylene Glycol, Propylparaben, Retinyl Palmitate, Sorbitan Sesquioleate, Tocopheryl Acetate, Water.

Questions?

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

Renew Periprotect Package Label Principal Display Panel



PERIPROTECT™

SKIN PROTECTANT
MOISTURE BARRIER CREAM

DermaRite^{*}

REORDER #00435

CONTENTS: 12 TUBES - 113 g (4 oz.) Each



10714196004359

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

MADE IN THE USA 100434



PERIPROTECT™

SKIN PROTECTANT
MOISTURE BARRIER CREAM

NDC 61924-435-04

Drug Facts

Active ingredient Purpose
Zinc Oxide 12% Skin Protectant
Dimethicone 1% Skin Protectant

USCS ■ Helps treat and prevent diaper rash.
■ Protects minor skin irritation associated with diaper rash and helps seal out wetness.

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

Directions ■ Change wet and soiled diapers promptly, cleanse the diaper area and allow to dry. ■ Apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

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 Aloe Barbadensis Leaf Juice, Aluminum Stearate, Beeswax, Cholecalciferol, Chloroxylenol, Com Oil, Imidazolidinyl Urea, Fragrance, Lanolin, Methylparaben, Mineral Oll, Paraffin Wax, Petrolatum, Phenoxyethanol, Propylene Glycol, Propylparaben, Retinyl Palmitate, Sorbitan Sesquioleate, Tocopheryl Acetate, Water.

Questions? Call 800-337-6296 Mon - Frl 9AM - 5PM EST.



REORDER #00435

Net Wt. 113 g (4 oz.)



DermaRite Industries LLC • 7777 West Side Avenue North Bergen, NJ 07047 = www.dermarite.com MADE IN THE USA 100234

RENEW PERIPROTECT

skin protectant ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61924-435
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12 g in 100 g	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	1 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
2-PHENYLPROPANAL PROPYLENE GLYCOL ACETAL (UNII: 1Z RR9A405A)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
TOCOPHERYL RETINOATE (UNII: 0WN694NBMM)	
WATER (UNII: 059QF0KO0R)	
N-(1,3,4-TRIS(HYDROXYMETHYL)-2,5-DIOXO-4-IMIDAZOLIDINYL)-N,N'-BIS(HYDROXYMETHYL)UREA (UNII: ENL2IA4WGW)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: 1900E3H2ZE)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
ALOE VERA LEAF POLYSACCHARIDES (UNII: W210437517)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CORN OIL (UNII: 8470G57WFM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
LANOLIN (UNII: 7EV65EAW6H)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-435- 04	114 g in 1 TUBE; Type 0: Not a Combination Product	10/18/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/18/2016	

Labeler - DermaRite Industries, LLC (883925562)

Registrant - DermaRite Industries, LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
DermaRite Industries, LLC		883925562	manufacture(61924-435)

Revised: 1/2022 DermaRite Industries, LLC