

RENEW DIMETHICONE SKIN PROTECTANT- skin protectant cream
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.

DRUG LISTING: Renew Dimethicone Skin Protectant

Active Ingredient:

Dimethicone 5%

Purpose:

Skin Protectant

Uses:

- Forms a moisture barrier that prevents and helps treat effects associated with diaper rash from wetness, urine, or stool.
- Temporarily protects and helps relieve chapped or cracked skin.

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 or does not improve within 7 days.
- **Do not use** on deep or punctured wounds.

Warnings:

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

Directions:

Clean skin gently with mild skin cleanser. Pat dry or allow to air dry. Apply as necessary. If applying to perineal area, apply after each incontinent episode or diaper change to promote comfort and long lasting protection.

Other Information:

Store at room temperature (59 °- 86 °F)

Inactive Ingredients:

Aloe Barbadensis Leaf Juice, Aluminum Stearate, Cera Alba, Cholecalciferol, Chloroxylenol, Corn Oil, Imidiazolidinyl Urea, Dicaprylyl Sebacate, Dicaprylyl Citrate, Fragrance, Lanolin, Methylparaben, Mineral Oil, Paraffin wax, Petrolatum, Phenoxyethanol, Propylene Glycol, Propylparaben, Retinyl Palmitate, Sorbitan Sesquioleate, Tocopheryl Acetate, Water.

Questions?

Call 1-800-37-6296

Renew Skin Protectant Package Label Principal Display Panel



**DIMETHICONE
SKIN PROTECTANT**
with VITAMINS A,D, & E
+
ESSENTIAL OILS

LATEX FREE
DERMATOLOGIST TESTED

DermaRite

REORDER #00410

4 OZ (113g)

NDC 61924-410-04

Drug Facts

Active Ingredient	Purpose
Dimethicone 5%	Skin Protectant

Uses ■ Forms a moisture barrier that prevents and helps treat effects associated with diaper rash from wetness, urine, or stool. ■ Temporarily protects and helps relieve chapped or cracked skin.

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 or does not improve within 7 days.

Do not use on deep or puncture wounds.

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

Directions Clean skin gently with mild skin cleanser. Pat dry or allow to air dry. Apply as necessary. If applying to the perineal area, apply after each incontinent episode or diaper change to promote comfort and long lasting protection.

Other Information

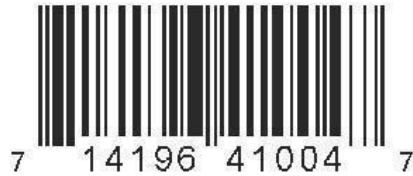
Store at room temperature (59°-86°F).

Inactive Ingredients Aloe Barbadosis Leaf Juice, Ascorbyl Palmitate, Butylparaben, Canola Oil, Carbomer, Cetearyl Alcohol, Cholecalciferol, Ethylparaben, Fragrance, Glycerin, Glyceryl Stearate, Isobutylparaben, Methylparaben, Niacinamide, Olea Europaea (Olive) Oil, PEG-100 Stearate, Phenoxyethanol, Propylene Glycol, Propylparaben, Pyridoxine HCl, Retinyl Palmitate, Stearic Acid, Tocopheryl Acetate, Triethanolamine, Versene Na2 Crystals, Water, Zea Mays (Corn) Oil

Questions? Call 800-337-6296

Patient
Name

Room #



DermaRite Industries LLC
Paterson, NJ 07514
www.dermaRite.com

**MADE
IN THE
USA**

Renew™

DIMETHICONE SKIN PROTECTANT

with VITAMINS A, D, & E

+

ESSENTIAL OILS

DermaRite®

REORDER #00410

CONTENTS: 12 TUBES - 4 OZ (113 g) Each



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

DermaRite Industries LLC
Paterson, NJ 07514
800.337.6296
www.dermarite.com

**MADE
IN THE
USA**

RENEW DIMETHICONE SKIN PROTECTANT

skin protectant cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61924-410
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.05 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLPARABEN (UNII: 3QPHU3FV8)	
CANOLA OIL (UNII: 331KBJ17RK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0K00R)	
CORN OIL (UNII: 8470G57WFM)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-410-05	5 g in 1 PACKET; Type 0: Not a Combination Product	03/15/2012	
2	NDC:61924-410-04	113 g in 1 TUBE; Type 0: Not a Combination Product	03/15/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/15/2012	

Labeler - Dermalite Industries LLC (883925562)

Registrant - Dermalite Industries LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
Dermalite Industries LLC		883925562	manufacture(61924-410)

Revised: 1/2020

Dermalite Industries LLC