

RENEW SKIN REPAIR- otc skin protectant drug products 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 SKIN REPAIR CREAM

Active Ingredient:

Dimethicone 1.5%

Purpose:

Skin Protectant

Uses:

Temporarily protects and helps relieve chapped or cracked skin. Beneficial for face, hands, body, and legs.

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 and if symptoms clear up and occur again within a few days.
- Do not use on deep or punctured wounds, animal bites, or serious burns.

Warnings:

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

Directions:

Apply cream liberally 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 :

Water, Olea Europaea(Olive) Oil, Zea Mays (Corn) Oil, Canola Oil, Stearic Acid, glyceryl Stearate, PEG-100 Stearate, Propylene Glycol, Triethanolamine, Aloe Barbadensis Leaf Juice, Glycerin, Butylparaben, Ethylparaben, Isobutylparaben, methylparaben, Phenoxyethanol, propylparaben, Citrus Aurantium Dulcis (orange) Peel Oil, Anthemis Nobilis Flower Oil, Lavandula Officinalis (lavender) Oil, Fragrance, Cetearyl Alcohol, Carbomer, Ascorbyl Palmitate, Disodium EDTA, Tocopheryl Acetate, Niacinamide, Retinyl Palmitate, Cholecalciferol, Pyridoxine HCL

Questions?

Call 1-800-337-6296 Mon-Fri 9AM-5PM EST.

Package Label Principal Display Panel

Renew[™]

SKIN REPAIR CREAM
+
ESSENTIAL OILS

SKIN PROTECTANT
EVERY DAY MOISTURIZER
Nurtures and Conditions Dry, Cracked Skin

DermaRite

REORDER #00408 Net Wt. 907 g (32 oz.)

NDC 61924-405-32

Drug Facts	
Active Ingredient	Purpose
Dimethicone 1.8%	Skin Protectant
Uses	
Temporarily protects and helps relieve chapped or cracked skin. Beneficial for face, hands, body, and legs.	
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 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 cream liberally as needed.	
Other information	
Store at room temperature (59°-86°F).	
You may report a serious adverse event to DermaRite Industries, PO Box 2205, North Bergen, NJ 07047.	
Inactive Ingredients Water, Olea Europaea (Olive) Oil, Zea Mays (Corn) Oil, Canola Oil, Stearic Acid, Glyceryl Stearate, PEG-100 Stearate, Propylene Glycol, Triethanolamine, Aloe Barbadosensis Leaf Juice, Glycerin, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxymethol, Propylparaben, Citrus Aurantium Dulcis (Orange) Peel Oil, Anthemis Nobilis Flower Oil, Lavandula Officinalis (Lavender) Oil, Fragrance, Cetylalcohol, Carbomer, Ascorbyl Palmitate, Disodium EDTA, Tocopheryl Acetate, Niacinamide, Rastrolol Palmitate, Cholecalciferol, Polidocaine, HCl	
Questions? Call 1-800-337-6296 Mon - Fri 9AM - 6PM EST.	



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

MADE
IN THE
USA
100682

Room #
Patient Name

Renew™



Drug Facts	
Active ingredient	Purpose
Dimethicone 1.5%	Skin Protectant
Uses	
<ul style="list-style-type: none"> Temporarily protects and helps relieve chapped or cracked skin. Beneficial for face, hands, body, and legs. 	
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 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 cream liberally as needed.	
Other information	
<ul style="list-style-type: none"> Store at room temperature (59°-86°F). You may report a serious adverse event to DermaRite Industries, PO Box 7208, North Bergen, NJ 07047. 	
Inactive Ingredients Water, Olea Europaea (Olive) Oil, Zea Mays (Corn) Oil, Canola Oil, Stearic Acid, Glycerol Stearate, PEG-100 Stearate, Propylene Glycol, Triethanolamine, Aloe Barbadensis Leaf Juice, Glycerin, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Propylparaben, Citrus Aurantium Dulcis (Orange) Peel Oil, Anthemis Nobilis Flower Oil, Lavandula Officinalis (Lavender) Oil, Fragrance, Cetearyl Alcohol, Carbomer, Ascorbyl Palmitate, Disodium EDTA, Tocopheryl Acetate, Niacinamide, Retinyl Palmitate, Cholecalciferol, Pyridoxine HCl	
Questions? Call 1-800-337-8286 Mon - Fri 9AM - 5PM EST.	

SKIN REPAIR CREAM



ESSENTIAL OILS

SKIN PROTECTANT EVERY DAY MOISTURIZER

Nurtures and Conditions Dry, Cracked Skin

DermaRite®

REORDER # 00407BB

800 mL (27 fl. oz.)

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



**MADE
IN THE
USA**
101482

LOADING INSTRUCTIONS

- 1 Open dispenser by pushing buttons on the bottom right and left of the dispenser.
- 2 Position bag in dispenser with nozzle facing you.
- 3 Press nozzle tip firmly into bottom groove in dispenser. Snap into place.
- 4 Close dispenser cover and push handle several times to prime pump.



NDC 61924-405-05

Drug Facts	
Active ingredient	Purpose
Dimethicone 1.5%	Skin Protectant
Uses	
<ul style="list-style-type: none"> Temporarily protects and helps relieve chapped or cracked skin. Beneficial for face, hands, body, and legs. 	
Warnings For external use only. Avoid contact with eyes. In case of contact, flush thoroughly with water. Stop use and ask a doctor if <ul style="list-style-type: none"> 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 cuts. Keep Out of Reach of Children. In case of accidental ingestion contact a physician or Poison Control Center right away.	
Directions Apply cream liberally as needed.	
Other information	
<ul style="list-style-type: none"> Store at room temperature (59°-86°F). You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047. 	
Questions? Call 1-800-337-6298 Mon - Fri 9AM - 5PM EST.	

FRONT PANEL

REORDER #00400 5 g (0.18 oz.)

DermaRite Industries LLC 7777 West Side Ave. **MADE IN THE USA**
 North Bergen, NJ 07047 www.dermarite.com 1001332

Renew™

SKIN REPAIR CREAM
+
ESSENTIAL OILS

SKIN PROTECTANT
EVERY DAY MOISTURIZER

Nurtures and Conditions
Dry, Cracked Skin

DermaRite®

REORDER #00405 Net Wt. 113 g (4 oz.)

NDC 61924-405-04

Drug Facts	
<i>Active Ingredient</i>	<i>Purpose</i>
Dimethicone 1.5%	Skin Protectant
Uses	
■ Temporarily protects and helps relieve chapped or cracked skin. Beneficial for face, hands, body, and legs.	
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 cream liberally 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 Water, Olea Europaea (Olive) Oil, Zea Mays (Corn) Oil, Canola Oil, Stearic Acid, Glyceryl Stearate, PEG-100 Stearate, Propylene Glycol, Triethanolamine, Aloe Barbadensis Leaf Juice, Glycerin, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxylethanol, Propylparaben, Citrus Aurantium Dulcis (Orange) Peel Oil, Anthemis Nobilis Flower Oil, Lavandula Officinalis (Lavender) Oil, Fragrance, Cetearyl Alcohol, Carbomer, Ascorbyl Palmitate, Disodium EDTA, Tocopheryl Acetate, Niacinamide, Retinyl Palmitate, Cholecalciferol, Pyridoxine HCl	
Questions? Call 1-800-337-6296 Mon - Fri 9AM - 5PM EST.	

Patient
Name

Room #



7 14196 40504 3

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North Bergen, NJ 07047 • www.dermarite.com

**MADE
IN THE
USA**
100832

RENEW SKIN REPAIR

otc skin protectant drug products cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61924-405
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.015 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYL PARABEN (UNII: 3QP1IU3FV8)	
CANOLA OIL (UNII: 331KBJ17RK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
ETHYL PARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (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:61924-405-27	793 g in 1 BAG; Type 0: Not a Combination Product	03/03/2011	
2	NDC:61924-405-04	113 g in 1 TUBE; Type 0: Not a Combination Product	03/03/2011	
	NDC:61924-405-	007 g in 1 BOTTLE; Type 0: Not a Combination Product		

3	NDC:61924-405-32	907 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/03/2011	
4	NDC:61924-405-05	5 g in 1 PACKET; Type 0: Not a Combination Product	03/03/2011	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	03/03/2011		

Labeler - Dermarite Industries LLC (883925562)

Registrant - Dermarite Industries LLC (883925562)

Establishment			
Name	Address	ID/FEI	Business Operations
Dermarite Industries LLC		883925562	manufacture(61924-405)

Revised: 1/2020

Dermarite Industries LLC