

MEDLINE REMEDY PHYTOPLEX SKIN REPAIR- dimeticone cream

Medline Industries, LP

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.

995 Remedy® with Phytoplex® Intensive Skin Therapy Skin Repair Cream

Active ingredient

Dimethicone 5%

Purpose

Skin protectant

Uses

- temporarily protects and helps relieve chapped or cracked skin. Protects from the drying effects of wind and cold weather.

Warnings

- **For external use only**

Do not use

- on deep or puncture wounds
- on animal bites
- on serious burns

Stop use and ask a doctor if

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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply as needed

Other information

Protect from freezing. Avoid excessive heat.

Inactive ingredients

aphanizomenon flos-aquae (algae) extract, bisabolol, brassica campestris (rapeseed) sterols, camellia sinensis (green tea) leaf extract, caprylic/capric triglycerides, caprylyl glycol, carthamus tinctorius (safflower) oleosomes, cetyl alcohol, cetylhydroxyproline palmitamide, cholecalciferol, cocos nucifera (coconut oil), 7-dehydrocholesterol, eugenia caryophyllus (clove) flower extract, glycerin, glyceryl stearate, glycol distearate, 1,2-hexanediol, hexyldecanol, hydrolyzed soy protein, hydroxyacetophenone, jojoba esters, manuka honey, olea europaea (olive oil), peg 100 stearate, phospholipids, phytonadione, propanediol, stearic acid, tocopherol acetate, water, yeast ferment extract, zea mays (corn) oil

Manufacturing Information

Phytoplex, Medline Remedy, and Medline are registered trademarks of Medline Industries Inc.

Manufactured for: Medline Industries, Inc., Three Lakes Drive, Northfield, IL 60093 USA.

Made in USA of domestic and imported materials.

WWW.medline.com 1-800-MEDLINE

RK20BLB

Package Labels

NDC 53329-995-84



Intensive Skin Therapy

Skin Repair Cream

For dry, cracked skin

With
Phytoplex®
Nutrition

Beneficial for Hands, Body and Legs

CHG Compatible • Hypoallergenic

Paraben Free • Fragrance Free

Pediatrician Tested • For All Ages

33.8 fl oz (1000 mL)



Drug Facts

Active ingredient

Dimethicone 5% Skin Protectant

Purpose

Uses ■ temporarily protects and helps relieve chapped or cracked skin.
■ helps protect from the drying effects of wind and cold weather.

Warnings ■ For external use only

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

When using this product ■ avoid contact with the eyes

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ apply as needed

Other information

Inactive ingredients aphanizomenon flos-aquae (algae) extract, bisabolol, brassica campestris (rapeseed) sterols, camellia sinensis (green tea) leaf extract, caprylic/capric triglycerides, caprylyl glycol, carthamus tinctorius (saflower) oleosomes, cetyl alcohol, cetylhydroxyproline palmitamide, cholecalciferol, cocos nucifera (coconut oil), 7-dehydrocholesterol, eugenia caryophyllus (clove) flower extract, glycerin, glyceryl stearate, glycol distearate, 1,2-hexanediol, hexyldecanol, hydrolyzed soy protein, hydroxyacetophenone, jojoba esters, manuka honey, olea europaea (olive oil), peg 100 stearate, phospholipids, phytonadione, propanediol, stearic acid, tocopherol acetate, water, yeast ferment extract, zea mays (corn) oil

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REF MSC0924434UNS



MEDLINE REMEDY PHYTOPLEX SKIN REPAIR

dimeticone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-995
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HEXANEDIOL (UNII: ZIA319275I)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CORN OIL (UNII: 8470G57WFM)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATER (UNII: 059QF0KO0R)	
APHANIZOMENON FLOSAQUAE (UNII: 49VG1X560X)	
LEVOMENOL (UNII: 24WE03BX2T)	
HEXYLDECANOL (UNII: 151Z7P1317)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
RAPESEED STEROL (UNII: B46B6DD20U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHYTONADIONE (UNII: A034SE7857)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETYLHYDROXYPROLINE PALMITAMIDE (UNII: 74ONU0S62G)	
CLOVE (UNII: K48IKT5321)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COCONUT OIL (UNII: Q9L0O73W7L)	
7-DEHYDROCHOLESTEROL (UNII: BK1IU07GKF)	
GLYCERIN (UNII: PDC6A3C0OX)	
JOJOBA OIL (UNII: 724GKU717M)	
HONEY (UNII: Y9H1V576FH)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-995-04	118 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2019	
2	NDC:53329-995-13	59 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2019	
3	NDC:53329-995-23	946 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2019	
4	NDC:53329-995-84	1000 mL in 1 BAG; Type 0: Not a Combination Product	11/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	11/01/2019	

Labeler - Medline Industries, LP (025460908)

Revised: 12/2022

Medline Industries, LP