

RENUEE - dimethicone cream
PMC TRADE, EXPORT AND IMPORT

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 FACTS

Active Ingredient

Dimethicone 2%

Purpose

Skin protectant

Use

- helps prevent, temporarily protects and relieve chafed, chapped, or cracked skin

Warnings

For external use only

When using this product

- do not get into eyes

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 or puncture wounds ■ animal bites ■ serious burns

If pregnant or breast feeding

ask a health professional before use

Keep out of reach of children

to avoid accidental poisoning, in case of accidental ingestion contact a doctor or Poison Control Center immediately.

Directions

apply as needed

Inactive Ingredients

Deionized Water, Aloe Vera (Aloe Barbadensis) Leaf Gel, Gotu Kola (Centella Asiatica) Extract,

Seaweed (*Fucus Vesiculosus*) Extract, Ginkgo biloba, Shea (*Butyrospermum Parkii*) Butter, Cocoa (*Theobroma Cacao*) Butter, Caffeine, Sweet Almond (*Prunus Amygdalus Dulcis*) Oil, Xanthan Gum, Tetrasodium EDTA, Elderberry (*Sambucus Nigra*) Extract, Jojoba Esters, Glycerin, Green Tea (*Camellia Sinensis*) Leaf Extract, Horsetail (*Equisetum Arvense*) Extract, Hydrolyzed Wheat Proteins, Tocopheryl Acetate (Vitamin E), Acrylates Copolymer, Propylene Glycol, SD-Alcohol 40B, Triethanolamine, Fragrance, DMDM Hydantoin, Caramel Color, D&C Orange #4, FD&C Yellow #5

Product Label




ÉTERNELLE
 PHARMA
 2% Dimethicone Cream

RENUÉE[®]
 REESTRUCTIL TECHNOLOGIES[™]

Prevent and temporarily protect cracked, chafed and chapped skin

- ✓ moisturize
- ✓ hide uneven tones
- ✓ smooth & soften, stretch marks

NET WT 3.1 oz. (90g)



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Dist by:
PMC Trade Export and Import
 Doral, FL 33178
LOT NO. EXP.

Preserve the environment.
 Recycle empty packaging after use.




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RENUÉE

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68973-002	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	2 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CENTELLA ASIATICA (UNII: 7M867G6T1U)				
FUCUS VESICULOSUS (UNII: 535G2ABX9M)				
GINKGO BILOBA WHOLE (UNII: 660486U6OI)				
SHEA BUTTER (UNII: K49155WL9Y)				
CAFFEINE (UNII: 3G6A5W338E)				
ALMOND OIL (UNII: 66YXD4DKO9)				
XANTHAN GUM (UNII: TTV12P4NEE)				
EDETATE SODIUM (UNII: MP1J8420LU)				
SAMBUCUS NIGRA FLOWERING TOP (UNII: CT03BSA18U)				
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)				
GLYCERIN (UNII: PDC6A3C0OX)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
EQUISETUM ARVENSE BRANCH (UNII: 1L0VKZ185E)				
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
TROLAMINE (UNII: 9O3K93S3TK)				
DMDM HYDANTOIN (UNII: BYR0546TOW)				
D&C ORANGE NO. 11 (UNII: B16H36W4W4)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68973-002-90	90 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	07/15/2014		

Labeler - PMC TRADE, EXPORT AND IMPORT (179635003)

