DIMETHICONE AND PETROLATUM- dimethicone and petrolatum cream Greenbrier International, Inc.

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.

FOOT CREAM

Drug Facts

Active Ingredients

Dimethicone 1%

White petrolatum 30%

Purpose

Skin protectant

Uses

• helps relieve, prevent and temporarily protect chafed, chapped or cracked skin

Warnings

For external use only

For adult use only

Do not use on

- Ideep or puncture wounds
- animal bites
- serious burns

When using this product

avoid contact with eyes.

Stop use and ask a doctor if

- condition worsens
- redness, irritation, swelling or pain persists or increases
- symptoms persist 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 generously to affected area as needed

Other information

• store at 20 °C-25 °C (68 °F to 77 °F)

Inactive Ingredients

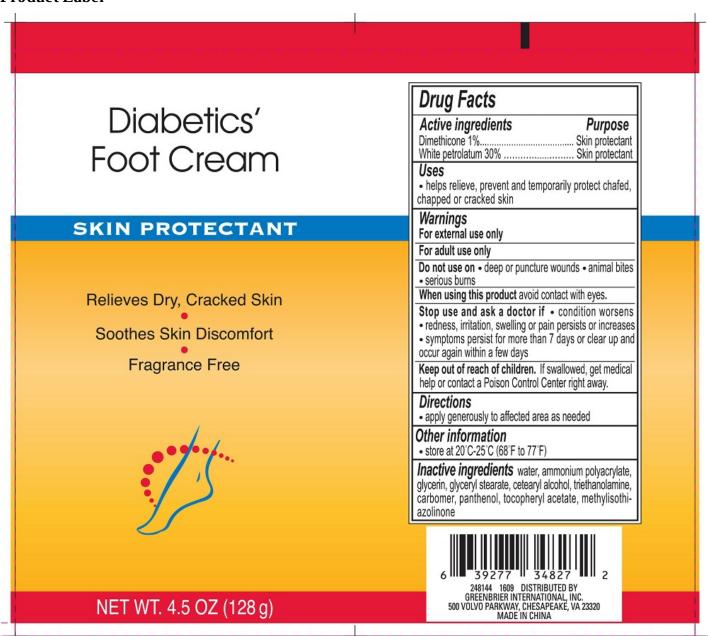
water, ammonium polyacrylate, glycerin, glyceryl stearate, cetearyl alcohol, triethanolamine, carbomer, panthenol, tocopheryl acetate, methylisothiazolinone

Distributed By

GREENBRIER INTERNATIONAL, INC. 500 VOLVO PARKWAY, CHESAPEAKE, VA 23320 MADE IN CHINA

Diabetics' Foot Cream SKIN PROTECTANT NET WT. 4.5 OZ (128 g)

Product Label



DIMETHICONE AND PETROLATUM

dimethicone and petrolatum cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-8918	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	38.4 g in 128 g		
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1.28 g in 128 g		

Inactive Ingredients			
Ingredient Name	Strength		
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)			
PANTHENOL (UNII: WV9CM0O67Z)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
WATER (UNII: 059QF0KO0R)			
TROLAMINE (UNII: 9O3K93S3TK)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)			
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)			

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:33992-8918-1	128 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 2/20 19	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	0 1/0 2/20 19		

Labeler - Greenbrier International, Inc. (610322518)

Establishment

Name	Address	ID/FEI	Business Operations
Lab Douce Cosmetics (Shenzhen) Co., Ltd.		529303186	manufacture(33992-8918)

Revised: 12/2019 Greenbrier International, Inc.