

DIABETICS FOOT CREAM 4 OZ- dimethicone, petrolatum lotion BRANDS INTERNATIONAL

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.

KISSABLE -Diabetics' Foot Cream 4 oz

☐ Active Ingredient Purpose

Dimethicone 1% Skin Protectant

Petrolatum 30%.....Skin Protectant

Skin protectant

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

☐ **Use** help prevent and temporarily protects chafed, chapped, or cracked skin.

☐ **Warnings For external use only.**

When using this product avoid contact with eyes. In case of eye contact, flush with water.

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

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.

☐ **Directions** apply liberally as often as needed.

☐ **Other information** Store at room temperature.

☐ **Inactive Ingredients** Water, Ceterayl Alcohol, Glycerin, Isopropyl Myristate, DMDM Hydantoin, Carbomer, Sodium Hydroxide, Aloe Vera Leaf , Vitamin E.

Drug Facts

Active Ingredients.....Purpose
 Dimethicone 1.0%.....Skin Protectant
 Petrolatum 30.0%.....Skin Protectant

Use help prevent and temporarily protects chafes, chapped, or cracked skin.

Warnings
 For external use only
 When using this product avoid contact with eyes. In case of eye contact, flush with water.
 Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns
 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.
 Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions
 ■ apply liberally as often as needed

Other information ■ store at room temperature.

Inactive Ingredients Water, Cetearyl Alcohol, Glycerin, Isopropyl Myristate, Cetreath-20, Stearic Acid, Carbomer, Sodium Hydroxide, DMDM Hydantoin, Aloe Vera Leaf Extract, Vitamin E.

Manufactured By: / Fabriqué Par :
 Brands International Corp.
 Newmarket, ON, L3X 2S2
www.brandscorp.com
 Made in Canada

3mm

DIABETICS FOOT CREAM 4 OZ

dimethicone, petrolatum lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50157-610
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	30 g in 100 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
LAURETH-7 (UNII: Z95S6G8201)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CARBOMER 1342 (UNII: 809Y72KV36)	
.ALPHA.-ELEOSTEARIC ACID (UNII: 934U1Q8QHG)	
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)	
VITAMIN E POLYETHYLENE GLYCOL SUCCINATE (UNII: O03S90U1F2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-610-11	113 g in 1 TUBE; Type 0: Not a Combination Product	02/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/22/2023	

Labeler - BRANDS INTERNATIONAL (243748238)

Registrant - BRANDS INTERNATIONAL (243748238)

Establishment

Name	Address	ID/FEI	Business Operations
BRANDS INTERNATIONAL		243748238	manufacture(50157-610)

Revised: 2/2023

BRANDS INTERNATIONAL