FOOTSCRIPTIONS FOOT REPAIR- menthol cream Donegal Bay Ltd

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.

Daily Moisturizing Lotion

Active Ingredient:

Menthol USP 0.1%

Purpose:

External Analgesic

Uses:

Temporarily relieves pain and itching associated with skin irritations

Warnings:

For external use only

When using this product, avoid contacting with eyes

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

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Direction:

Adults and children 2 years and older: apply up to 3-4 times daily.

Under 2 years: ask a doctor

Wash and dry feet, apply liberally over feet, between toes, on bottoms of feet, and message until absorbed.

Inactive Ingredients:

Aloe Barbadenis Leaf Juice, Water, Mineral Oil, Glycerryl Stearate, PEG-100 Stearate, Cetyl Alcohol, Cetearyl Alcohol, Polysorbate 60, Propylene Glycol, Stearic Acid, Hydrogenated Polyisobutene, Dimethicone, Triethanolamine, Salicylic Acid, Imidazlidinyl, Urea, Chondrus Crispus, Methylparaben, Propylparaben, Mentha Piperita (peppermint) Oil, Chloroxylenol, DMDM Hydantoin



FOOT REPAIR CREAM

FAST ACTING RELIEF FOR:

- DrynessCracks
- Odors Itching



Footscriptions will:

- Repair dry, cracked feet & heels
- Help stop itching & unpleasant odors
- Rejuvenate tired, achy feet

Podiatrist Endorsed



External Analgesic

FOOTSCRIPTIONS™ Prescription for Healthy Feet

FOOT REPAIR CREAM with 70% Maximum Aloe

Relieve dry, cracked, tired, itchy, achy feet, and odor. FOOTSCRIPTIONS™ exclusive formulation contains 70% of the finest and most efficient form of Aloe Vera Gel - Maximum Aloe - with additional moisturizer, effectively penetrating through to under layers of skin accelerating the repair of dry cracked feet and heels. Footscriptions™ also rejuvenates tired, achy feet, stopping foot odor, leaving your feet smelling fresh and feeling thier best



This product is manufactured and distributed by Donegal Bay, owner of FOOTSCRIPTIONS TAX



No Animal Testing



Tested donegal bay

Cleveland, OH 44128 www.donegalbayusa.com









net wt. 8.5 oz./ 252 mL

FOOTSCRIPTIONS FOOT REPAIR

menthol cream

Product Information

Product Type HUMAN OTC DRUG NDC:70990-002 Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	0.1 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE ANDONGENSIS LEAF (UNII: N1P4NU25EJ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYDRO GENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
UREA (UNII: 8W8T17847W)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
CHLOROXYLENOL (UNII: 0F32U78 V2Q)	
DMDM HYDANTO IN (UNII: BYR0 546 TOW)	

Packaging					
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:70990-002-01	252 mL in 1 TUBE; Type 0: Not a Combination Product	10/12/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	10/12/2016		

Labeler - Donegal Bay Ltd (068443618)

Registrant - Donegal Bay Ltd (068443618)

Establishment					
Name	Address	ID/FEI	Business Operations		
HANGZHOU KARIC COMMODITIES CO., LTD		526884335	manufacture(70990-002)		

Revised: 10/2016 Donegal Bay Ltd