

BLISTERZONE- skin protectant stick
MedZone Products LLC

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.

Active Ingredient

Dimethicone 1%

Purpose

Skin Protectant

Uses

Temporarily protects and helps relieve chapped or cracked skin. Helps protect from the drying effects of wind and cold weather,

Warnings

DRUG FACTS

Active Ingredient	Purpose
Dimethicone 1%	Skin Protectant

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

When using this product:
• do not get into eyes

Stop use and ask a physician 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 • serious burns • animal bites

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

Directions: Apply liberally as needed before athletic activity or to areas of repetitive friction/rubbing.

Inactive Ingredients: Aloe Vera Leaf, Alpha-Tocopheryl Acetate, 1-Butene, C18-36 Acid Triglyceride, Ethylene, Eucalyptus Oil, Ginkgo, Levomenol, Medium-Chain Triglycerides, Menthyl Lactate, Methylparaben, Mineral Oil, Peppermint Oil, Petrolatum, Propylene, Propylparaben, Styrene, Tea Tree Oil, Tribehenin, Yellow Wax.

Other Information: Store at room temperature. Avoid excessive heat.

Questions? Toll-Free 866-MEDZONE (866-633-9663)
www.medzonecorp.com • info@medzonecorp.com
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BLISTERZONE

skin protectant stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70338-611
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
STYRENE (UNII: 44LJ2U959V)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
1-BUTENE (UNII: LY001N554L)	
ETHYLENE (UNII: 91GW059KN7)	
C18-36 ACID TRIGLYCERIDE (UNII: ZRA72DR3R7)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GINKGO (UNII: 19FUJ2C58T)	
LEVOMENOL (UNII: 24WE03BX2T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE (UNII: AUG1H506LY)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
TEA TREE OIL (UNII: VIF565UC2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70338-611-00	23 g in 1 APPLICATOR; Type 0: Not a Combination Product	07/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/01/2016	

Labeler - MedZone Products LLC (080083739)

Registrant - Richard Hamer Associates LLC (067731889)

Establishment

Name	Address	ID/FEI	Business Operations
Biomed Laboratories LLC		055329696	manufacture(70338-611) , pack(70338-611)

Establishment

Name	Address	ID/FEI	Business Operations
Micro Consult Inc		062183608	analysis(70338-611)

Establishment

Name	Address	ID/FEI	Business Operations
Ceutical Laboratories Inc		789485153	analysis(70338-611)

Revised: 2/2018

MedZone Products LLC