

CHAFEZONE CHUB RUB- 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.

ChafeZone ChubRub

DRUG FACTS

Active Ingredient

Active Ingredient	Purpose
Dimethicone 1%	Skin Protectant

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

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 Barbadosis Leaf Juice, Beeswax, Benzoic Acid, BHT, Bisabolol, Butylene/ethylene/styrene Copolymer, Caprylic Capric Triglyceride, C18-36 Acid Triglyceride, ethylene/propylene/styrene copolymer, ethylhexylglycerin, eucalyptus oil, ginkgo biloba leaf extract, glycereth-2 cocoate, glycerin, tea tree leaf oil, peppermint oil, Menthyl lactate, mineral oil, petrolatum, phenoxyethanol, tocopheryl acetate, tribehenin.

Other Information:

Store at room temperature. Avoid excessive heat.

Questions?

Toll-Free 866-MEDZONE (866-633-9663)

www.medzonecorp.com info@medzonecorp.com

Distributed by

MedZone Products, LLC

Lenexa, Kansas 66215

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DRUG FACTS	
Active Ingredient Ondocetone 1%	Purpose Skin Protectant
Uses Temporarily protects and helps relieve chapped or cracked skin. Helps protect skin in the drying effects of wind and cold weather.	
Warnings For external use only. Do not get into eyes.	
When using this product 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 sensitive skin rubbing.	
Inactive Ingredients: Aloe Barbadosis Leaf Juice, Beeswax, Benzoic Acid, BHT, Bisabolol, Butylene/ethylene/styrene Copolymer, C18-36 Acid Triglyceride, Caprylic/Capric Triglyceride, Ethylhexylglycerin, Eucalyptus Oil, Ginkgo Biloba Leaf Extract, Glycereth-2 Cocoate, Mineral Oil, Menthyl Lactate, Petrolatum, Phenoxyethanol, Tocopheryl Acetate, Tribehenin.	
Other Information: Store at room temperature. Avoid excessive heat. Questions? Toll-Free 866-MEDZONE (866-633-9663). www.medzonecorp.com • info@medzonecorp.com Distributed by MedZone Products LLC Lenexa, Kansas 66215. All Rights Reserved.	
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CHAFEZONE CHUB RUB

skin protectant stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70338-632
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
BENZOIC ACID (UNII: 8SKN0B0MIM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
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)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE (UNII: AUG1H506LY)	
STYRENE (UNII: 44LJ2U959V)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
TEA TREE OIL (UNII: VIF565UC2G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
1-BUTENE (UNII: LY001N554L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70338-632-01	43 g in 1 APPLICATOR; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2019	

Labeler - Medzone Products LLC (080083739)

Establishment

Name	Address	ID/FEI	Business Operations
Dhaliwal Laboratories LLC		016754201	manufacture(70338-632)