SKINDURANCE- dimethicone stick
Skindure, 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.

Skindurance

Active Ingredient

Dimethicone (1%)

Purpose

Skin Protectant

Uses

• Helps prevent and temporarily protects and helps relieve chafed, 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 doctor 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 • animal bites • serious burns.

Keep out of reach of children.

Directions

• Apply as needed

Inactive Ingredients

Caprylic/Capric Triglycerides, C18-36 Acid Triglycerides, Tribehenin, Aloe Barbadensis Leaf Extract, Jojoba Wax, Allantoin, Tocopheryl Acetate, Retinyl Palmitate, Hamamelis Virginiana (Witch Haxel) Leaf Extract

Other Information

Protect this product from excessive heat and direct sun.

Questions or Comments?

Call 301-247-9677

Made in America

Net Wt 2.5 oz. (70.9 g)

Drug Facts

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Distributor: **Skindure, LLC. Rockville, MD, USA**
 • www.skindurance.us • Made in the USA

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SKINDURANCE

dimethicone stick

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69802-025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 mg in 100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
C18-36 ACID TRIGLYCERIDE (UNII: ZRA72DR3R7)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
JOJOBA OIL (UNII: 724GKU717M)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69802-025-01	7090 mg in 1 APPLICATOR; Type 0: Not a Combination Product	05/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/01/2015	

Labeler - Skindure, LLC (079763592)

Revised: 4/2015 Skindure, LLC