NORML SHIELD- dimethicone cream MPM Medical 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.

MP00022 MPM NormIshield Skin Protectant 4 oz (update DUNS)

Active Ingredient

Dimethicone 4.5%

Purpose

Skin protectant

Uses

Helps prevent and temporarily protects chafed, chapped or cracked skin

Warnings

For external use only.

Keep out of reach of children.

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

Directions

Adults and children 2 years of age and older: Cleanse affected area. Allow to dry. Apply MPM NormIShield® liberally. Apply as needed.

Children under 2 years of age: Consult a physician prior to use.

Other Information

Store at room temperature.

Inactive Ingredients

Aloe barbadensis leaf extract, Cetearyl alcohol and polysorbate 60, Cetyl alcohol, Deionized water, DMDM hydantoin, Glycol stearate, Imidiazolidinyl urea, Isopropyl palmitate, Methylparaben, Mineral oil, PEG-40 hydrogenated castor oil, Propylene glycol, Propylparaben, Stearic acid, Stearyl Alcohol, Tocopheryl acetate, Triethanolamine

Package Label

NDC 66977-022-04



Drug Facts

Active ingredient

Purpose

Dimethicone 4.5% Skin protectant

Uses Helps prevent and temporarily protects chafed, chapped or cracked skin.

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

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

Directions Adults and children 2 years of age or older Cleanse affected area. Allow to dry. Apply MPM Norm|Shield® liberally, Apply as needed. Children under 2 years consult a physician prior to use.

Other information Store at room temperature

Inactive ingredients Aloe barbadensis leaf extract. Cetearyl alcohol and polysorbate 60, Cetyl alcohol, Deionized water, DMDM hydantoin, Glycol stearate, Imidiazolidinyl urea, Isopropyl palmitate, Methylparaben, Mineral oil, PEG-40 hydrogenated castor oil, Propylene glycol, Propylparaben, Stearic acid, Stearyl alcohol, Tocopheryl acetate, Triethanolamine

MANUFACTURED FOR:

R0618

MPM Medical Mesquite, TX 75149 www.mpmmed.com 800.232.5512 **REORDER NO. MP00022**



NORML SHIELD

dimethicone cream

Product	Information
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:66977-022

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	45 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
WATER (UNII: 059QF0KO0R)		
DMDM HYDANTOIN (UNII: BYR0546TOW)		
GLYCOL STEARATE (UNII: 0324G66D0E)		
IMIDUREA (UNII: M629807ATL)		
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
MINERAL OIL (UNII: T5L8T28FGP)		
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
TROLAMINE (UNII: 903K93S3TK)		

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:66977-022- 04	113 g in 1 TUBE; Type 0: Not a Combination Product	02/01/1993		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	02/01/1993		

Labeler - MPM Medical LLC (081241522)

Revised: 3/2022 MPM Medical LLC