

**SPA MYSTIQUE SKIN PROTECTION SOOTHING RELIEF MOISTURIZING -
dimethicone cream**

Volume Distributors, Inc.

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.

SPA Mystique Skin Protection Soothing Relief Moisturizing Cream

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Active Ingredient

Dimethicone.....1.3%

Purpose

Skin protectant

Use

Help prevent and temporarily protects chafed, chapped, or cracked skin.

Warnings

For external use only.

When using this product

avoid contact with eyes. In case of eye contact, flush with water.

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.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

apply liberally as often as needed.

Other information

Store at room temperature.

Inactive ingredients

Avena Sativa Kernel Extract, Paraffinum Liquidum, Isopropyl Myristate, Glycerin, Glyceryl Stearate, Propylene Glycol, PEG-100 Stearate, Polyacrylamide, Cetyl Alcohol, Fragrance, DMDM Hydantoin, Stearyl Alcohol, C13-14 Isoparaffin, Laureth-7, Disodium EDTA, Iodopropynyl Butylcarbamate, Water



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SPA MYSTIQUE SKIN PROTECTION SOOTHING RELIEF MOISTURIZING
dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50523-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
OAT (UNII: Z6J799EAJK)	
MINERAL OIL (UNII: T5L8T28FGP)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50523-101-08	235 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/09/2013	

Labeler - Volume Distributors, Inc. (002029544)