

BEING WELL BODY DAILY MOISTURIZING- dimethicone lotion
Save-A-Lot Food Stores Ltd

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 1.25%

Purpose

Skin protectant

Uses

- Helps prevent and temporarily protects chafed, chapped, or cracked skin
- Helps prevent and 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. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions Apply as needed

Inactive ingredients avena sativa (oat) kernel flour, benzyl alcohol, cetearth-20, cetrimonium chloride, cetyl alcohol, FD&C blue no.1, FD&C yellow no.5, FD&C yellow no.6, glycerin, isopropyl palmitate, methylchloroisothiazolinone, methylisothiazolinone, petrolatum, triethanolamine, water



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dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46994-500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1.25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)				
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)				
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)				
PETROLATUM (UNII: 4T6H12BN9U)				
TROLAMINE (UNII: 9O3K93S3TK)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46994-500-12	355 mL in 1 BOTTLE, PLASTIC		
2	NDC:46994-500-18	532 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part347		03/01/2013	

Labeler - Save-A-Lot Food Stores Ltd (095484572)