

LUCKY DAILY MOISTURIZING- dimethicone lotion
Delta Brands 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.

DRUG FACTS

Active Ingredient

Dimethicone 1%

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, carbomer, cetareth-20, cetrimonium chloride, cetearyl alcohol, FD&C blue no.1, FD&C yellow no.5, FD&C yellow no.6, glycerin, methylchloroisothiazolinone, methylisothiazolinone, mineral oil, petrolatum, p glycol, triethanolamine, tocopheryl acetate, water

Product Label



LUCKY DAILY MOISTURIZING			
dimethicone lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20276-044

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20276-044-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2013	
2	NDC:20276-044-18	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2013	
3	NDC:20276-044-08	227 mL in 1 TUBE; Type 0: Not a Combination Product	07/15/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	01/31/2013	

Labeler - Delta Brands Inc (102672008)