

DAILY MOISTURIZING- dimethicone lotion
TopCo Associates 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.

Drug Facts Top Care 619.003/619AC rev 2

Active ingredient

Dimethicone 1.3%

Purpose

Skin Protectant

Uses

- helps prevent and temporarily protects chafed, chapped, cracked or cracked skin
- helps protect from the drying effects of wind and cold weather

Warnings

For external use only

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

When using this product

keep out of eyes

Stop use and ask a doctor if

condition worsens or does not improve within seven days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

apply liberally as often as necessary

Inactive ingredients

water, glycerin, distearyldimonium chloride, petrolatum, isopropyl palmitate, cetyl alcohol, Avena sativa (oat) kernel flour, benzyl alcohol, sodium chloride

Disclaimer

This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company, distributor of Aveno Daily Moisturizing Lotion

Made in the USA with US and foreign components

Adverse Reactions

DIST. BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

QUESTIONS? 1-888-423-0139 topcare@topco.com

www.topccarebrand.com

619.003/619AC rev 2

principal display panel

TOPCARE

beauty

DAILY

MOISTURIZING

LOTION

Dimethicone Skin Protectant

Compare to AVEENO

With natural colloidal oatmeal

Dermatologist tested

Fragrance

Free

18 FL OZ (1 PT 2 FL OZ) 532 mL



DAILY MOISTURIZING LOTION

Dimethicone Skin Protectant

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+

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Free

18 FL OZ (1 PT 2 FL OZ) 532 mL

L0019836FA

DAILY MOISTURIZING

dimethicone lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:36800-619

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	13.13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OATMEAL (UNII: 8PI54V663Y)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-619-44	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/03/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/03/2010	

Labeler - TopCo Associates LLC (006935977)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(36800-619)