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

Active ingredient

Active ingredient

Dimethicone 1.3%

Purpose

Purpose

Skin Protectant

Uses

Uses helps prevent and temprarily protects chafed, chapped, cracked or windburned skin.

Warnings

Warnings

For external use only

Do not use

Do not use on deep or puncture wounds, infections, or lacerations. Consult a doctor

When using this product

Wen using this product keep out of eyes

Stop use

Stop use and ask a doctor if condition worsens or does not improve within seven days

Keep out of reach of children

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

Directions

Directions apply liberally as often at necessary

Inactive ingredients

Inactive ingredients avena sativa (oat)kernel flour, benzyl alcohol, cetyl alcohol, distearyldimonium

chloride, glycerin, isopropyl palmitate, petrolaturm, sodium chloride, water

Disclaimer

This product is not manufactured or distributed by Johnon + 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, 7711 GROSS POINT ROADK, SKOKIE 60077
QUESTIONS? 1-888-423-0139 topcare@topco.com

Principal Display Panel

TopCare

TONE + TEXTURE

daily

moisturizing

body lotion

fragrance free

dermatologist tested

with natural colloidal oatmeal

relieves and protects dry skin

SKIN PROTECTANT

COMPARE TO AVEENO

12 FL OZ (354 mL)





DAILY MOISTURIZING

dimethicone lotion

Product Information

Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:36800-619

Route of Administration TOPICAL DEA Schedule

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICO NE (DIMETHICONE)	DIMETHICONE	13.13 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
OATMEAL	
BENZYL ALCOHOL	
CETYL ALCOHOL	

DISTEARYLDIMONIUM CHLORIDE	l l
GLYCERIN	
ISOPROPYL PALMITATE	
SO DIUM CHLO RIDE	
WATER	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36800-619-40	354 mL in 1 BOTTLE, PUMP		

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)

Revised: 2/2013 TopCo Associates LLC