

**SKIN CARE EXTRA STRENGTH- dimethicone lotion
THE KROGER CO**

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.

BACK LABEL - DRUG FACTS BOX

ACTIVE INGREDIENT

DIMETHICONE 1.0%

WARNING

FOR EXTERNAL USE ONLY.

When using this product

AVOID CONTACT WITH EYES, IF CONTACT OCCURS, RINSE EYE THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

CONDITION WORSENS OR SYMPTOMS PERSIST FOR MORE THAN SEVEN DAYS OR OCCUR AGAIN WITHIN A FEW DAYS.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Purpose

Skin Protectant

Uses

HELPS PREVENT AND TEMPORARILY PROTECTS CHAFED, CHAPPED OR CRACKED SKIN

Directions

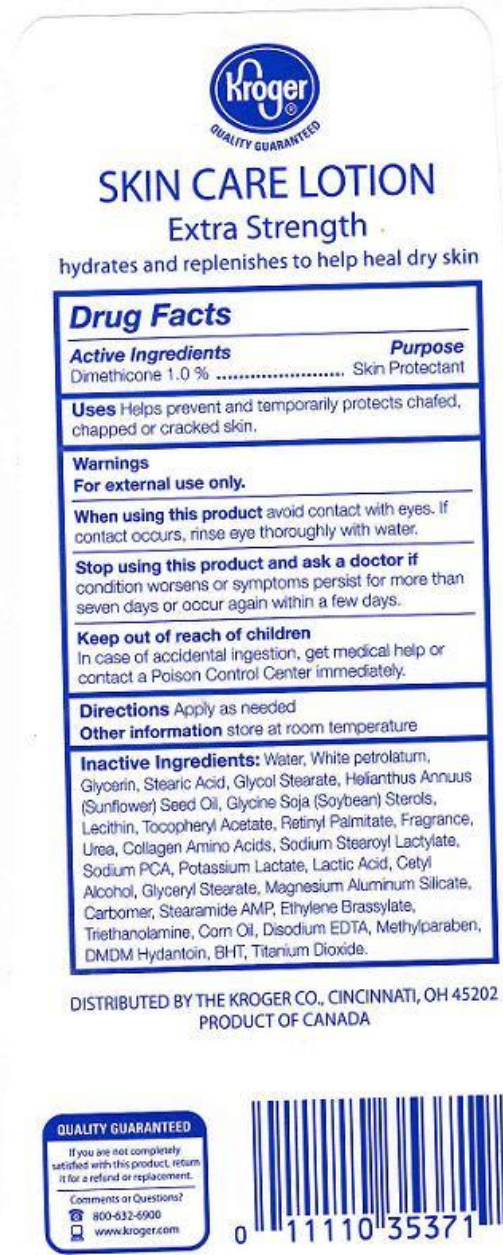
APPLY AS NEEDED.

Inactive Ingredients

Water, White Petrolatum, Glycerin, Stearic Acid, Glycol Stearate, Helianthus Annuus (Sunflower) Seed Oil, Glycine Soja (Soybean) Sterols, Lecithin, Tocopheryl Acetate, Retinyl Palmitate, Fragrance, Urea, Collagen Amino Acids, Sodium Stearoyl Lactylate, Sodium PCA, Potassium Lactate, Lactic Acid, Cetyl Alcohol, Glyceryl Stearate, Magnesium Aluminum Silicate, Carbomer, Stearamide AMP, Ethylene Brassylate, Triethanolamine, Corn Oil, Disodium EDTA, Methylparaben, DMDM Hydantoin, BHT, Titanium Dioxide

Package Front and Back Labels

24OZ Front and Back Labels: k24.jpg



SKIN CARE LOTION
Extra Strength

hydrates and replenishes to help heal dry skin

Drug Facts

Active Ingredients
Dimethicone 1.0 % Skin Protectant

Uses Helps prevent and temporarily protects chafed, chapped or cracked skin.

Warnings
For external use only.

When using this product avoid contact with eyes. If contact occurs, rinse eye thoroughly with water.

Stop using this product and ask a doctor if condition worsens or symptoms persist for more than seven days or occur again within a few days.

Keep out of reach of children
In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions Apply as needed
Other information store at room temperature

Inactive Ingredients: Water, White petrolatum, Glycerin, Stearic Acid, Glycol Stearate, Helianthus Annuus (Sunflower) Seed Oil, Glycine Soja (Soybean) Sterols, Lecithin, Tocopheryl Acetate, Retinyl Palmitate, Fragrance, Urea, Collagen Amino Acids, Sodium Stearoyl Lactylate, Sodium PCA, Potassium Lactate, Lactic Acid, Cetyl Alcohol, Glyceryl Stearate, Magnesium Aluminum Silicate, Carbomer, Stearamide AMP, Ethylene Brassylate, Triethanolamine, Corn Oil, Disodium EDTA, Methylparaben, DMDM Hydantoin, BHT, Titanium Dioxide.

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OH 45202
PRODUCT OF CANADA



SKIN CARE EXTRA STRENGTH
dimethicone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59450-315
Route of Administration	TOPICAL		

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
SOY STEROL (UNII: PL360EPO9J)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
UREA (UNII: 8W8T17847W)	
SODIUM ISOSTEAROYL LACTYLATE (UNII: 8730J0D3EV)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
POTASSIUM LACTATE (UNII: 87V1KMK4QV)	
LACTIC ACID (UNII: 33X04XA5AT)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
CARBOMER 934 (UNII: Z135WT9208)	
STEARAMIDOETHYL DIETHYLAMINE (UNII: 25FFJ4209Z)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
TROLAMINE (UNII: 9O3K93S3TK)	
CORN OIL (UNII: 8470G57WFM)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59450-315-24	709 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/25/2010	

Labeler - THE KROGER CO (006999528)