

DERMASIL- dimethicone lotion
Rise International Group 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.

Dermasil® Labs

Dermasil® Labs has developed Dermasil® OTC pharmaceuticals skincare, a powerful dry skin treatment and skin protectant.

This lotion contains four systems to control and provide long-lasting relief from severe dry skin:

Occlusives to block moisture loss from the skin's surface

Humectant to bind water in the skin's outermost layers

Skin Lipids to enhance the skin's natural ability to retain moisture

EFA's an important component of the skin's moisture barrier

Indications:

Suitable for severe dry skin, and control of symptoms such as chapping, cracking, flaking, roughness, redness, soreness, and the itching associated with dry skin.

Drug Facts

Active Ingredient

Dimethicone 1 %

Purpose

Skin Protectant

Uses

- Temporarily protects and helps relieve chapped or cracked skin.
- Helps protect from the drying effects of wind and cold weather.

Warnings

- For external use only.
- 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.

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

Directions

- Apply as needed

Inactive Ingredients

Water (Aqua), Petrolatum, Mineral Oil (Paraffinum Liquidum), Glycerin, Stearic Acid, Glycol Stearate, Glyceryl Stearate, PEG-40 Stearate, Cetyl Alcohol, Phenoxyethanol, Methylisothiazolinone, Iodopropynyl Butylcarbamate, Magnesium Aluminum Silicate, Helianthus Annuus (Sunflower) Seed Oil, Cetyl Acetate, Sodium Hydroxide, Acetylated Lanolin Alcohol, Carbomer, Disodium EDTA, Geranium Maculatum Oil, Lecithin, Borago Officinalis Seed Oil, Cholesterol, Ascorbyl Palmitate, Prunus

Amygdalus Dulcis (Sweet Almond) Oil, Ethylene Brassylate, Santalum Album (Sandalwood) Oil, Rosa Damascena Extract, Vanilla Planifolia Fruit Extract



Cruelty-Free. No Animal Testing.

Please Recycle This Bottle.

www.riseintlgroup.com

RISE INTERNATIONAL GROUP LLC

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Questions/Comments? 1-800-282-1813

Principal Display Panel - Tube Label Dermasil 10oz

25% MORE

Dermasil®

LABS

Pharmaceutical Research

Controls Even Severe Dry Skin

Skin Lipid & EFA Treatment

Hypo-Allergenic

Dermasil®

Dry Skin Treatment

ORIGINAL LOTION

10 FL OZ (296 ml)

25 %
MORE



Pharmaceutical Research

Controls Even Severe Dry Skin
Skin Lipid & EFA Treatment
Hypo-Allergenic

Dermasil[®]
Dry Skin Treatment
ORIGINAL LOTION

10 FL OZ (296 ml)

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- Occlusives** to block moisture loss from the skin's surface
- Humectant** to bind water in the skin's outermost layers
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- EFA's** an important component of the skin's moisture barrier

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INACTIVE INGREDIENTS: WATER (AQUA), GLYCERIN, PETROLATUM, MINERAL OIL (PARAFFINUM LIQUIDUM), STEARIC ACID, GLYCOL STEARATE, GLYCERYL STEARATE, PEG-40 STEARATE, CETYL ALCOHOL, CETYL ACETATE, SODIUM HYDROXIDE, PHENOXYETHANOL, CARBOMER, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, DISODIUM EDTA, ACETYLATED LANOLIN ALCOHOL, GERANIUM MACULATUM OIL, METHYLISOTHIAZOLINONE, IODOPROPYNYL BUTYL CARBAMATE, MAGNESIUM ALUMINUM SILICATE, LECITHIN, BORAGO OFFICINALIS SEED OIL, CHOLESTEROL, ASCORBYL PALMITATE, PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL, ETHYLENE BRASSYLATE, SANTALUM ALBUM (SANDALWOOD) OIL, ROSA DAMASCENA EXTRACT, VANILLA PLANIFOLIA FRUIT EXTRACT.

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Questions/Comments? 1-800-282-1813



Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67143-2101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.01 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CETYLPYRIDINIUM ACETATE (UNII: 6W29RZ7YU2)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
BORAGE (UNII: PB618V0K2W)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ALMOND (UNII: 3Z252A2K9G)	
VANILLA (UNII: Q74T35078H)	
GERANIUM MACULATUM ROOT (UNII: 93IXI5B6OJ)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67143-2101-4	296 mL in 1 TUBE		
2	NDC:67143-2101-6	274 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part347	10/15/2009	
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Labeler - Rise International Group LLC (011184988)

Establishment

Name	Address	ID/FEI	Business Operations
Kingkey Daily Chemical Co LTD		545349263	MANUFACTURE(67143-2101)

Revised: 1/2014

Rise International Group LLC