

DERMASIL SENSITIVE- 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 has developed Dermasil® OTC Sensitive Skin Formula, a powerful sensitive 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 sensitive 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, Sodium Hydroxide, Phenoxyethanol, Methylisothiazolinone, Iodopropynyl Butylcarbamate, Magnesium Aluminum Silicate, Allantoin, Helianthus Annuus (Sunflower) Seed Oil, Cetyl Acetate, Acetylated Lanolin Alcohol, Carbomer, Disodium EDTA, 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.

Questions/Comments? 1-800-282-1813

△Cruelty-Free. No Animal Testing.

Please Recycle This Bottle.

www.riseintlgroup.com

RISE INTERNATIONAL GROUP LLC

Lodi, NJ 07644. Made in China

©RISE INTERNATIONAL GROUP LLC

Principal Display Panel - Bottle Label Dermasil 8oz

Dermasil®

LABS

Pharmaceutical Research

Controls Even Severe Dry Skin

Skin Lipid & EFA Treatment

Hypo-Allergenic

Dermasil®

Sensitive Skin Treatment

LOTION

8 FL.OZ. (1/2 PINT, 237 ml)



Pharmaceutical Research

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

Dermasil®

Sensitive Skin Treatment

LOTION

8 FL.OZ. (1/2 PINT, 237ml)

Dermasil® Labs has developed **Dermasil® OTC Sensitive Skin Formula**, a powerful sensitive 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 sensitive skin, and control of symptoms such as chapping, cracking, flaking, roughness, redness, soreness, and the itching associated with dry skin.

Drug Facts

Active Ingredient	Purpose
Dimethicone 1%.....	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.

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, ALLANTOIN, ROSA DAMASCENA EXTRACT, DISODIUM EDTA, ACETYLATED LANOLIN ALCOHOL, METHYLISOTHIAZOLINONE, IODOPROPYNYL BUTYLCARBAMATE, MAGNESIUM ALUMINUM SILICATE, LECITHIN, BORAGO OFFICINALIS SEED OIL, CHOLESTEROL, ASCORBYL PALMITATE, PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL, ETHYLENE BRASSYLATE, SANTALUM ALBUM (SANDALWOOD) OIL, VANILLA PLANIFOLIA FRUIT EXTRACT.

Questions/Comments? 1-800-282-1813



Distributed by:
RISE INTERNATIONAL GROUP LLC
 Lodi, NJ 07644, USA
 Made in China
 at a USA FDA Approved Facility
 © RISE INTERNATIONAL GROUP LLC

Cruelty-Free. No Animal Testing.
 Please Recycle This Bottle.
www.riseintlgroup.com

DERMASIL SENSITIVE

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67143-3102
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: 059QF0K00R)
PETROLATUM (UNII: 4T6H12BN9U)
MINERAL OIL (UNII: T5L8T28FGP)
GLYCERIN (UNII: PDC6A3C0OX)
STEARIC ACID (UNII: 4ELV7Z65AP)
GLYCOL STEARATE (UNII: 0324G66D0E)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-40 STEARATE (UNII: ECU18C66Q7)
CETYL ALCOHOL (UNII: 936JST6JCN)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
MAGNESIUM (UNII: I38ZP9992A)
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)
ALLANTOIN (UNII: 344S277G0Z)
SUNFLOWER OIL (UNII: 3W1JG795Y)
CETYL OLEATE (UNII: 78K2L26L8N)
LANOLIN (UNII: 7EV65EAW6H)
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
EDETATE DISODIUM (UNII: 7FLD91C86K)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
BORAGE OIL (UNII: F8XAG1755S)
CHOLESTEROL (UNII: 97C5T2UQ7J)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
ALMOND OIL (UNII: 66YXD4DKO9)
SANDALWOOD OIL (UNII: X7X01WMQ5F)
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)
VANILLA (UNII: Q74T35078H)
SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67143-3102-2	237 mL in 1 BOTTLE		
2	NDC:67143-3102-3	237 mL in 1 TUBE		
3	NDC:67143-3102-5	214 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/15/2009	

Labeler - Rise International Group LLC (011184988)

Establishment

Name	Address	ID/FEI	Business Operations
Kingkey Daily Chemical Co., Ltd.		545349263	MANUFACTURE(67143-3102)

