

## **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.*

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Dermasil® Labs has developed Dermasil® OTC Sensitive Skin Formula, a powerful skin treatment treatment and 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, Sodium Hydroxide, Phenoxyethanol, Methylisothiazolinone, Iodopropynyl Butylcarbamate, Magnesium Aluminum Silicate, 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.



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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®**

**Sensitive Skin Treatment**

**LOTION**

10 FL OZ (296 ml)

25%  
MORE



Pharmaceutical Research

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

**Dermasil**<sup>®</sup>  
Sensitive Skin Treatment  
LOTION

10 FL OZ (296 ml)

Dermasil<sup>®</sup> Labs has developed **Dermasil<sup>®</sup> 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

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- 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 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,VANILLA PLANIFOLIA FRUIT EXTRACT.



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Questions/Comments? 1-800-282-1813



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Try our  
*Day/Night Face Cream!*



**DERMASIL SENSITIVE**

dimethicone lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67143-2102
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
dimethicone (UNII: 92RU3N3Y1O) (dimethicone - UNII:92RU3N3Y1O)	dimethicone	0.01 g in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MAGNESIUM (UNII: I38ZP9992A)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CETYL OLEATE (UNII: 78K2L26L8N)	
LANOLIN (UNII: 7EV65EAW6H)	
CARBOMER HOMO POLYMER 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)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67143-2102-4	296 mL in 1 TUBE		
2	NDC:67143-2102-6	274 mL in 1 TUBE		

## 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(67143-2102)

Revised: 1/2014

Rise International Group LLC