

SOOTHE SENSITIVE SKIN TREATMENT- allantoin, dimethicone lotion
Rodan & Fields

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 ingredients

Allantoin 0.5%

Dimethicone 2.9%

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

When using this product

- do not get into eyes

Stop use and ask doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply a thin, even layer over the entire face, avoiding the eye area. Do not rinse off. Use twice daily. Apply as needed.

Inactive ingredients

Water/Aqua/Eau, Glycerin, Isododecane, Sodium Acrylates Copolymer, Oryza Sativa (Rice) Bran Extract, Chamomilla Recutita (Matricaria) Flower Extract, Pelargonium Graveolens Flower Oil, Lavandula Angustifolia (Lavender) Oil, Boswellia Serrata Extract, Oligopeptide-10, Tetrapeptide-16, Tocopherol, Tropolone, Tranexamic Acid, Honey Extract, Glycine Soja (Soybean) Germ Extract,

Perilla Ocymoides Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Bisabolol, Angelica Polymorpha Sinensis Root Extract, Linoleic Acid, Linolenic Acid, Butylene Glycol, Coco-Caprylate/Caprates, Decyl Glucoside, Dimethylacrylamide/Acrylic Acid/Polystyrene Ethyl Methacrylate Copolymer, Hydrogenated Polyisobutene, Lysolecithin, PEG-40 Stearate, Phospholipids, Polyglyceryl-10 Stearate, Polysilicone-11, Xanthan Gum, Hexylene Glycol, Tin Oxide, 1,2-Hexanediol, Caprylyl Glycol, Chlorhexidine Digluconate, Chlorphenesin, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Citronellol, Geraniol, Linalool, Mica, Titanium Dioxide (CI 77891).

Other information

- Store between 15-30 °C (59-86 °F),
Do not refrigerate.

Principal Display Panel - Soothe Sensitive Skin Treatment Tube Label

RODAN+FIELDS®

SOOTHE

2

Sensitive Skin
Treatment



Principal Display Panel - Soothe Sensitive Skin Treatment Carton Label

RODAN+FIELDS®
SOOTHE

2
Sensitive
Skin
Treatment

RODAN+FIELDS®
Skin Protectant
50 mL/1.7 Fl. Oz.

Decide Today
How Tomorrow Looks™

Sensitive Skin Treatment
50 mL/1.7 Fl. Oz.

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Drug Facts (continued)

Soja (Soybean) Germ Extract, Perilla Ocyroides Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Bisabolol, Angelica Polymorpha Sinensis Root Extract, Linoleic Acid, Linolenic Acid, Butylene Glycol, Coco-Caprylate/Caprate, Decyl Glucoside, Dimethylacrylamide/Acrylic Acid/Polystyrene Ethyl Methacrylate Copolymer, Hydrogenated Polyisobutene, Lysolecithin, PEG-40 Stearate, Phospholipids, Polyglyceryl-10 Stearate, Polysilicone-11, Xanthan Gum, Hexylene Glycol, Tin Oxide, 1,2-Hexanediol, Caprylyl Glycol, Chlorhexidine Digluconate, Chlorphenesin, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Citronellol, Geraniol, Linalool, Mica, Titanium Dioxide (CI 77891).

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RODAN+FIELDS
SOOTHE
2 Sensitive
Skin
Treatment

Step 2 in the SOOTHE Regimen for Sensitive Skin. Hydrating lotion with exclusive RFP3 peptide technology helps to heal the visible signs of dry, irritated, sensitive skin. Dimethicone and allantoin fortify the skin's barrier to relieve dryness and reduce the signs of sensitivity. Optical filters effectively neutralize the look of visible redness. Suitable for sensitive skin types and conditions. Use as part of the SOOTHE Regimen for best results.

Developed by Stanford-trained dermatologists Dr. Katie Rodan and Dr. Kathy Fields.

Dist. Rodan & Fields, LLC
San Francisco, CA 94105
SOTTO50 8000-06-0029
Please Recycle

QUESTIONS OR COMMENTS
1-888-995-5656

RODAN+FIELDS

Skin Protectant
50 mL/1.7 Fl. Oz.

visit rodanandfields.com



6000-06-2068

SOOTHE SENSITIVE SKIN TREATMENT

allantoin, dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14222-1005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z)	Allantoin	0.5 g in 100 mL
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	2.9 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Isododecane (UNII: A8289P68Y2)	
Rice Bran (UNII: R60QEP13IC)	
Chamomile (UNII: FGL3685T2X)	
Pelargonium Graveolens Flower Oil (UNII: 3K0J1S7QGC)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Indian Frankincense (UNII: 4PW41QCO2M)	
Oligopeptide-10 (UNII: Q46328TRNK)	
Tocopherol (UNII: R0ZB2556P8)	
Tropolone (UNII: 7L6DL16P1T)	
Tranexamic Acid (UNII: 6T84R30KC1)	
Honey (UNII: Y9H1V576FH)	
Soybean Germ (UNII: JBW2VHD14M)	
Perilla Frutescens Seed Oil (UNII: 322MS57V7Z)	
Sunflower Oil (UNII: 3W1JG795YI)	
Levomenol (UNII: 24WE03BX2T)	
Angelica Sinensis Root (UNII: B66F4574UG)	
Linoleic Acid (UNII: 9KJL21T0QJ)	
Linolenic Acid (UNII: 0RBV727H71)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Coco-Caprylate/Caprate (UNII: 8D9H4QU99H)	
Decyl Glucoside (UNII: Z17H97EA6Y)	
Hydrogenated Polybutene (1300 MW) (UNII: 7D1YQ9Y5EZ)	
PEG-40 Stearate (UNII: ECU18C66Q7)	
Lecithin, Soybean (UNII: 1DI56QDM62)	
Polyglyceryl-10 Stearate (UNII: 90TF85HH91)	
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5)	
Xanthan Gum (UNII: TTV12P4NEE)	
Hexylene Glycol (UNII: KEH0A3F75J)	
Stannic Oxide (UNII: KM7N50LOS6)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
Caprylyl Glycol (UNII: 00YIU5438U)	

Chlorhexidine Gluconate (UNII: MOR84MUD8E)	
Chlorphenesin (UNII: I670DAL4SZ)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Sodium Benzoate (UNII: OJ245FE5EU)	
.Beta.-Citronellol, (R)- (UNII: P01OUT964K)	
Geraniol (UNII: L837108USY)	
Linalool, (+/-)- (UNII: D81QY6I88E)	
Mica (UNII: V8A1AW0880)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-1005-1	1 in 1 BOX	06/01/2017	
1	NDC:14222-1005-0	50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/01/2017	

Labeler - Rodan & Fields (051659584)

Revised: 7/2017

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