

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%

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 in 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

After cleansing, apply evenly to face until it blends into skin. Avoid eye area. Do not rinse. Use AM + PM. Reapply as needed.

Inactive ingredients

Annona Cherimola Fruit Extract, Aqua/Eau/Water, Ascorbic Acid, Benzoic Acid, Boswellia Serrata Extract, Butylene Glycol, Caprylyl Glycol, Chlorphenesin, Chlorphenesin, Citric Acid, Coco-Caprylate/Caprates, Decyl Glucoside, Dehydroacetic Acid, Dimethylacrylamide/Acrylic Acid/Polystyrene Ethyl Methacrylate Copolymer, Dipotassium Glycyrrhizate, Disodium Lauriminodipropionate Tocopheryl Phosphates, Glycerin, Glycyrrhetic Acid, Helianthus Annuus (Sunflower) Seed Oil, Hexylene Glycol, Honey Extract/Mel Extract/Extrait De Miel, Hydrogenated Polyisobutene, Isododecane, Linoleic Acid, Linolenic Acid, Ocimum Sanctum Leaf Extract, Oleic Acid, Oligopeptide-10, Oryza Sativa (Rice) Bran Extract, Palmitic Acid, Panthenol, PEG-40 Stearate, Phenoxyethanol, Phenyl Trimethicone, Phenylpropanol, Phoenix Dactylifera (Date) Seed Extract, Phospholipids, Polyglyceryl-10 Stearate, Polysilicone-11, Propanediol, Sodium Acrylates Copolymer, Sodium Benzoate, Sodium Citrate, Sodium Dehydroacetate, Stearic Acid, Synthetic Fluorophlogopite, Tetrapeptide-16, Tin Oxide, Titanium Dioxide, Titanium Dioxide, Tocopherol, Xanthan Gum.

Questions?

1-888-995-5656

Principal Display Panel - 50 mL Carton Label

RODAN+FIELDS

SOOTHE

Sensitive Skin Treatment

2

50 mL / 1.7 Fl. Oz U.S.

R+F

Drug Facts (continued)

Acid, Panthenol, PEG-40 Stearate, Phenoxyethanol, Phenyl Trimethicone, Phenylpropanol, Phoenix Dactylifera (Date) Seed Extract, Phospholipids, Polyglyceryl-10 Stearate, Polydimethylsiloxane-11, Propanediol, Sodium Acrylates Copolymer, Sodium Benzoate, Sodium Citrate, Sodium Dehydroacetate, Stearic Acid, Synthetic Fluorphlogopite, Tetrapeptide-16, Tin Oxide, Titanium Dioxide, Titanium Dioxide, Tocopherol, Xanthan Gum.

Questions?
1-888-995-5656

RODAN+FIELDS

Lightweight lotion softens + hydrates dry, sensitive skin as it instantly reduces visible redness. Enriched with Dimethicone + Allantoin to help protect + nourish skin's moisture barrier. Provides instant relief of irritation + sensitivity caused by dryness.

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

Drug Facts

| Active Ingredients | Purpose |
|-----------------------------------|-----------------|
| Allantoin 0.5%, Dimethicone 2% | 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 in 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
After cleansing, apply evenly to face until it blends into skin. Avoid eye area. Do not rinse. Use AM + PM. Reapply as needed.

Inactive ingredients
Annona Cherimola Fruit Extract, Aqua/Eau/Water, Ascorbic Acid, Benzoic Acid, Boswellia Serrata Extract, Butylene Glycol, Caprylyl Glycol, Chlorphenesin, Chlorphenesin, Citric Acid, Coco-Caprylate/Caprate, Decyl Glucoside, Dehydroacetic Acid, Dimethylacrylamide/Acrylic Acid/Polystyrene Ethyl Methacrylate Copolymer, Dipotassium Glycyrrhizate, Disodium Lauriminodipropionate Tocopheryl Phosphates, Glycerin, Glycyrrhetic Acid, Helianthus Annuus (Sunflower) Seed Oil, Hexylene Glycol, Honey Extract/Mel Extract/Extrait De Miel, Hydrogenated Polyisobutene, Isododecane, Linoleic Acid, Linolenic Acid, Ocimum Sanctum Leaf Extract, Oleic Acid, Oligopeptide-10, Oryza Sativa (Rice) Bran Extract, Palmitic

SOOTHE

Sensitive Skin Treatment

2

50 mL / 1.7 Fl. Oz. U.S.



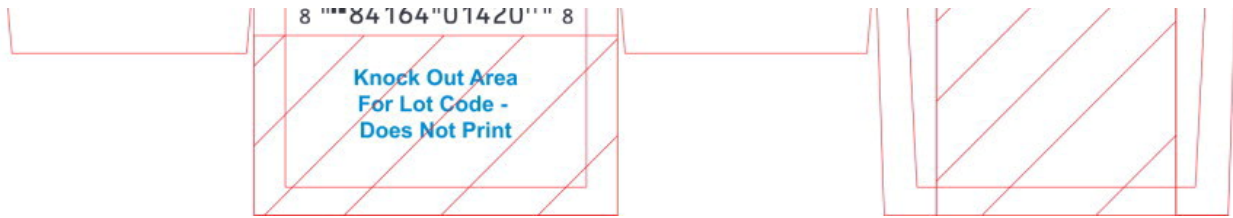
Dist. Rodan & Fields, LLC
San Francisco, CA 94105
Made in USA with US and Imported Materials
Please Recycle
rodanandfields.com
SOTT050 8000-06-0014
6000-06-0013 0B



0301154

0301154-6000-06-0013.pdf
CAD: RAF7038A





Principal Display Panel - 50 mL Bottle Label

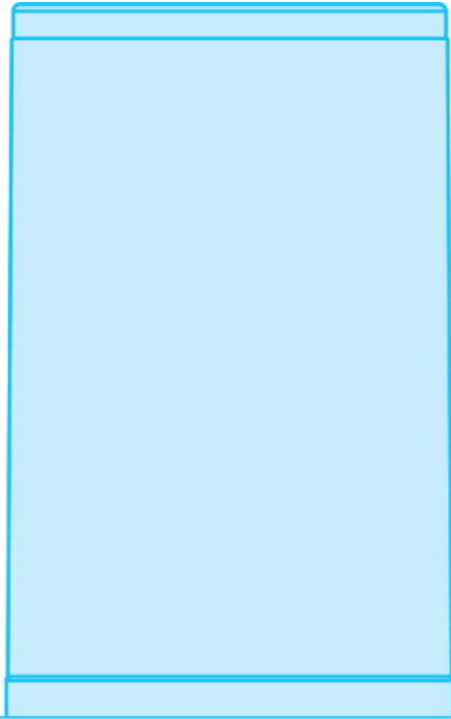
RODAN+FIELDS

SOOTHE

Sensitive Skin Treatment

Skin Protectant Lotion

2



NO PRINT AREA

RODAN+FIELDS

SOOTHE

Sensitive Skin Treatment



Active Ingredients: Allantoin 0.5%, Dimethicone 2% - Skin Protectants

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 in eyes. Stop use and ask doctor if condition worsens or if 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 or serious burns. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions: After cleansing, apply evenly to face until it blends into skin. Avoid eye area. Do not rinse. Use AM + PM. Reapply as needed.

NO PRINT AREA

Dist. Rodan & Fields, LLC
San Francisco, CA 94105

Made in USA with US and Imported Materials

Questions?

1-888-995-5656
rodanandfields.com

SOOTHE SENSITIVE SKIN TREATMENT

allantoin, dimethicone lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:14222-2420 |
| 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 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| CHERIMOYA (UNII: 33WWT714QS) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| INDIAN FRANKINCENSE (UNII: 4PW41QCO2M) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| CHLORPHENESIN (UNII: I670DAL4SZ) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H) | |
| DECYL GLUCOSIDE (UNII: Z17H97EA6Y) | |
| DEHYDROACETIC ACID (UNII: 2KAG279R6R) | |
| GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX) | |
| DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ENOXOLONE (UNII: P540XA09DR) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| HONEY (UNII: Y9H1V576FH) | |
| HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ) | |
| ISODODECANE (UNII: A8289P68Y2) | |
| LINOLEIC ACID (UNII: 9KJL21T0QJ) | |
| LINOLENIC ACID (UNII: 0RBV727H71) | |
| HOLY BASIL LEAF (UNII: SCJ765569P) | |
| OLEIC ACID (UNII: 2UMI9U37CP) | |
| OLIGOPEPTIDE-10 (UNII: Q46328TRNK) | |

| |
|--|
| RICE BRAN (UNII: R60QEP13IC) |
| PALMITIC ACID (UNII: 2V16EO95H1) |
| PANTHENOL (UNII: WV9CM0O67Z) |
| PEG-40 STEARATE (UNII: ECU18C66Q7) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |
| PHENYL TRIMETHICONE (UNII: DROK5NOJ4R) |
| PHENYLPROPANOL (UNII: 0F897O3O4M) |
| PHOENIX DACTYLIFERA SEED (UNII: 73NE6T0Q00) |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) |
| POLYGLYCERYL-10 STEARATE (UNII: 90TF85HH91) |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) |
| PROPANEDIOL (UNII: 5965N8W85T) |
| SODIUM BENZOATE (UNII: OJ245FE5EU) |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) |
| SODIUM DEHYDROACETATE (UNII: 8W46YN971G) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M) |
| STANNIC OXIDE (UNII: KM7N50LOS6) |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) |
| TOCOPHEROL (UNII: R0ZB2556P8) |
| WATER (UNII: 059QF0KO0R) |
| XANTHAN GUM (UNII: TTV12P4NEE) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:14222-2420-1 | 1 in 1 CARTON | 03/09/2021 | |
| 1 | | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:14222-2420-2 | 1 in 1 CARTON | 06/01/2021 | |
| 2 | | 10 mL in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:14222-2420-3 | 2 mL in 1 PACKET; Type 0: Not a Combination Product | 04/12/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 03/09/2021 | |

Labeler - Rodan & Fields (051659584)