

SOOTHE REGIMEN FOR SENSITIVE SKIN- allantoin, dimethicone, titanium dioxide, zinc oxide

Rodan & Fields

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

**Mineral Sunscreen Broad Spectrum SPF 30
+ Water Resistant (80 Minutes) 50 mL/1.7 Fl.Oz. U.S.**

Drug Facts

Active Ingredients

Titanium Dioxide 2%

Zinc Oxide 12%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove

Stop use and ask doctor if rash occurs

Keep out of reach of children.

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

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - After 80 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m.–2 p.m.
 - Wear long-sleeve shirts, pants, hats and sunglasses
- Children under 6 months: Ask a doctor

Other information

- Protect this product from excessive heat and direct sun.

Inactive ingredients

Cyclopentasiloxane, Water/Aqua/Eau, Cyclohexasiloxane, PEG-10 Dimethicone, Butylene Glycol, Dimethicone, Aluminum Starch Octenylsuccinate, Caprylyl Methicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Dipropylene Glycol, Glycerin, Camellia Sinensis Leaf Extract, Sodium Hyaluronate, Glycyrrhiza Glabra (Licorice) Root Extract, Dipotassium Glycyrrhizate, Panthenol, Tocopheryl Acetate, Sodium PCA, Hydrolyzed Wheat Protein/PVP Crosspolymer, Alumina, Distearidimonium Hectorite, Isoceteth-10, Methicone, Silica, Sodium Chloride, Disodium EDTA, Caprylyl Glycol, Ethylhexylglycerin, Potassium Sorbate, Phenoxyethanol, Methylparaben, Ethylparaben, Butylparaben.

Sensitive Skin Treatment

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

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.

Other information

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

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 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).

Moisture Replenishing Cream

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

Product Details

Directions

Apply a generous dime-sized amount evenly over the entire face every morning and evening, avoiding the eye area. Use after SOOTHE Gentle Cream Wash and SOOTHE Sensitive Skin Treatment, and follow with SOOTHE Mineral Sunscreen in the morning.

Warnings

For external use only. When using this product keep out of eyes. Rinse with water to remove. If irritation or rash occurs, discontinue use and consult your doctor. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Ingredients

Water/Aqua/Eau, Dimethicone, Glycerin, Pentylene Glycol, Ammonium Acryloyldimethyltaurate/VP Copolymer, Echium Plantagineum Seed Oil, Chamomilla Recutita (Matricaria) Flower Extract, Olea Europaea (Olive) Fruit Oil, Vitis Vinifera (Grape) Seed Oil, Pichia Anomala Extract, Ascorbyl Palmitate, Tocopherol, Triacetin, Hydrogenated Lecithin, Carnitine, Canola Oil/Huile de colza, Urea, Lecithin, Carbomer, Dimethicone/Vinyl Dimethicone Crosspolymer, Glyceryl Oleate, Glyceryl Stearate, Polysilicone-11, Sodium Hydroxide, Xanthan Gum, Citric Acid, BHT, Ethylhexylglycerin, Potassium Sorbate, Sodium Benzoate, Benzyl Alcohol, Phenoxyethanol.

Gentle Cream Wash

125 mL/4.2 Fl. Oz. U.S.

Product Details

Directions

Use in the morning and evening. Prior to using, remove any facial makeup. Apply a thin, even layer over entire face, avoiding the eye area. For oily skin, rinse thoroughly and pat dry. For dry skin, remove with a fresh, dry gauze pad.

Warnings

For external use only. When using this product keep out of eyes. Rinse with water to remove. If irritation or rash occurs, discontinue use and consult your doctor. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Ingredients

Water/Aqua/Eau, Caprylic/Capric Triglyceride, Glycerin, Cyclopentasiloxane, Propanediol, Isostearyl Alcohol, Aloe Barbadensis Leaf Juice, Ceramide NP, Ceramide EOP, Ceramide AP, Caffeine, Tocopheryl Acetate, Bisabolol, Butylene Glycol Cocoate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Xanthan Gum, Ethylcellulose, Aminomethyl Propanol, Sodium Lauroyl Lactylate, Tropolone, Phytosphingosine, Cholesterol, Carbomer, 1,2-Hexanediol, Caprylyl Glycol, Potassium Sorbate, Sodium Benzoate, Ethylhexylglycerin, Phenoxyethanol.

Principal display Panel - Rodan Fields Soothe Sensitive Skin Treatment Label

RODAN + FIELDS®
SOOTHE

2 Sensitive Skin
Treatment



RODAN + FIELDS®
SOOTHE

2 Sensitive Skin Treatment

Reduces the appearance of redness and calms irritation to help restore a smooth, clear, healthy-looking complexion.

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

DIRECTIONS: Apply a generous dime-sized amount evenly over the entire face, avoiding the eye area. Do not rinse off. Use twice daily.

ACTIVE INGREDIENTS: Allantoin 0.5%, Dimethicone 2.9% – Skin protectants

WARNINGS: For external use only. When using this product do not get into eyes. Stop use and ask doctor if condition worsens and 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 and serious burns. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Manufactured for Rodan & Fields, LLC
San Francisco, CA 94105
Made in USA SOTT050 85-06-0029 Please Recycle
visit rodanandfields.com

QUESTIONS OR COMMENTS 1-888-995-5656

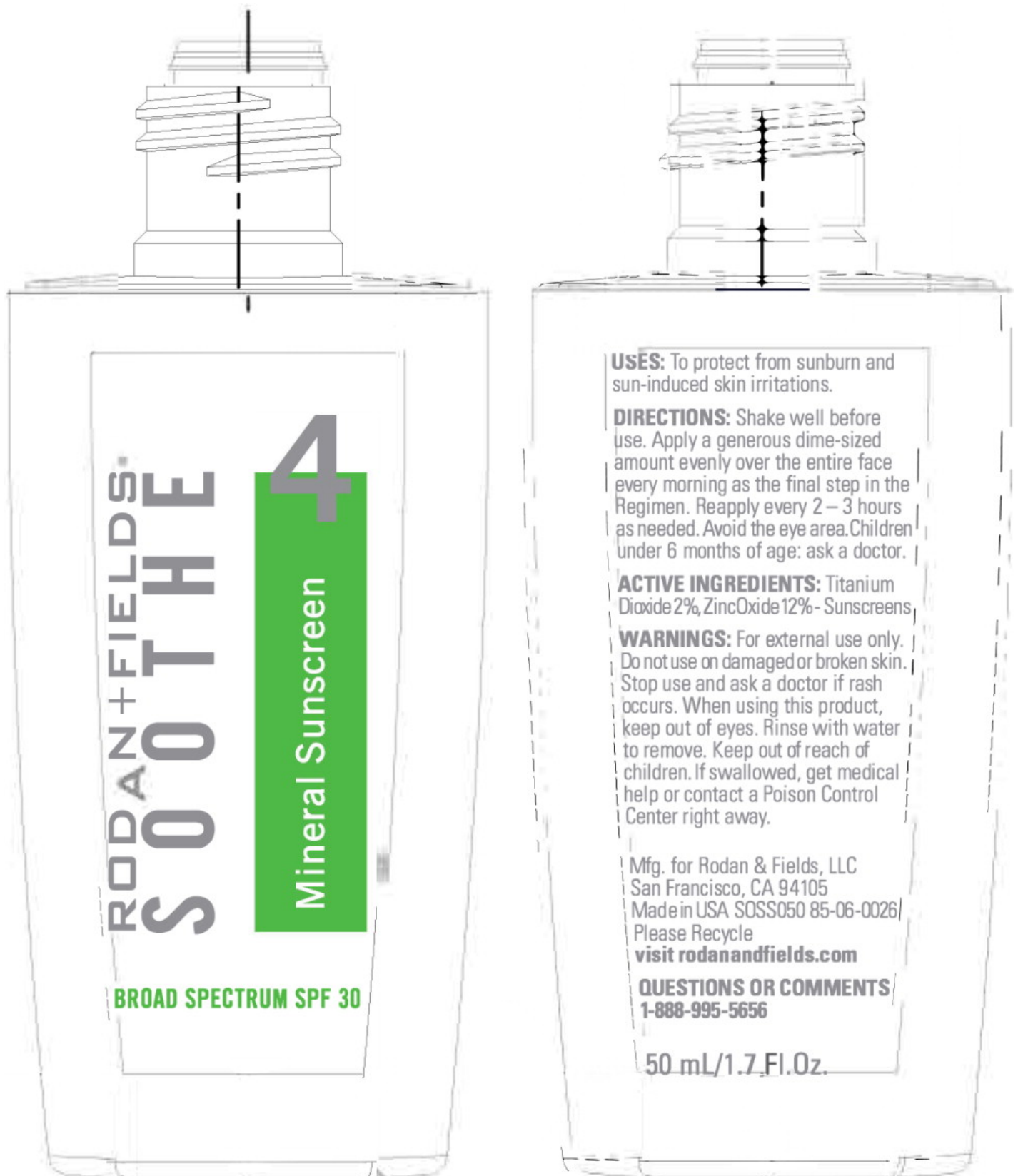
50 mL/1.7 Fl.Oz.

Principal display Panel - Rodan Fields Soothe Mineral Sunscreen Label

**RODAN + FIELDS®
SOOTHE**

**4
Mineral Sunscreen**

BROAD SPECTRUM SPF 30



Principal display Panel - Rodan Fields Soothe Carton Label

RODAN + FIELDS®
SOOTHE™

Regimen for Sensitive Skin

Based on Multi-Med® Therapy, **SOOTHE** is a complete skincare

system that uses clinically tested cosmetic and OTC ingredients to defend against dry, chapped, sensitive skin, and to soothe and calm visible facial redness.

This 4-product Regimen was developed by Stanford-trained dermatologists Dr. Katie Rodan and Dr. Kathy Fields.

RODAN + FIELDS®

Gentle Cream Wash

125 mL/
4.2 Fl.Oz. U.S.

Sensitive Skin Treatment
Skin Protectant

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

Moisture Replenishing Cream

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

Mineral Sunscreen Broad Spectrum
SPF 30 Water Resistant (80 Minutes)

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



SOOTHE REGIMEN FOR SENSITIVE SKIN

allantoin, dimethicone, titanium dioxide, zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14222-10 10
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-10 10-1	1 in 1 CARTON; Type 0: Not a Combination Product	06/01/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	50 mL
Part 2	1 TUBE	50 mL

Part 1 of 2

SENSITIVE SKIN TREATMENT

allantoin, dimethicone lotion

Product Information

Route of Administration	TOPICAL
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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/Caprates (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		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	

Part 2 of 2

MINERAL SUNSCREEN BROAD SPECTRUM SPF 30
titanium dioxide, zinc oxide lotion

Product Information

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	2 g in 100 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	12 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Water (UNII: 059QF0K00R)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
PEG-10 Dimethicone (600 CST) (UNII: 8PR7V1SVM0)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Dimethicone (UNII: 92RU3N3Y1O)	
Aluminum Starch Octenylsuccinate (UNII: I9PJ0O6294)	
Caprylyl Trisiloxane (UNII: Q95M2P1KJL)	
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4C00W6C5)	
Dipropylene Glycol (UNII: E107L85C40)	
Glycerin (UNII: PDC6A3C0OX)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Glycyrrhiza Glabra (UNII: 2788Z9758H)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	
Panthenol (UNII: WV9CM0O67Z)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Sodium Pyrrolidone Carboxylate (UNII: 469OTG57A2)	
Aluminum Oxide (UNII: LMI26O6933)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
Isoceteth-10 (UNII: 1K92T9919H)	
Methicone (20 CST) (UNII: 6777U11MKT)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Sodium Chloride (UNII: 451W47IQ8X)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Methylparaben (UNII: A218C7H9T)	
Ethylparaben (UNII: 14255EXE39)	
Butylparaben (UNII: 3QPI1U3FV8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	50 mL in 1 TUBE; Type 0: Not a Combination Product		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2017	

Labeler - Rodan & Fields (051659584)

Revised: 6/2017

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