

BEYOND THE SHAVE FOR MEN- sulfur, allantoin, dimethicone, avobenzone, homosalate, octisalate, octocrylene

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](#).

UNBLEMISH Acne Treatment Sulfur Wash

125 mL/4.2 Fl.Oz.

Drug Facts

Active ingredients

Sulfur 3%

Purpose

Acne Treatment

Uses

- For the treatment of acne.
- Helps keep skin clear of new acne blemishes, acne pimples, blackheads and whiteheads.

Warnings

For external use only

When using this product

- Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.
- Do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor.
- Apply only to areas with acne.

Do not use on

- Broken skin.
- Large areas of the skin.

Keep out of reach of children.

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

Directions

Wet skin with lukewarm water. Using fingertips, gently and evenly massage a quarter-sized amount onto entire face for 30 – 60 seconds, avoiding contact with eyes. Rinse thoroughly; pat dry. Use once daily and increase to twice daily as tolerated.

Inactive ingredients

Water/Aqua/Eau, Sodium Laureth Sulfate, Propylene Glycol, Distearyl Phthalic Acid Amide, Lauryl Glucoside, Aloe Barbadensis Leaf Juice, Diisodecyl Adipate, Glycerin, Hydrogenated Polyisobutene, Polyacrylamide, Cetearyl Alcohol, Titanium Dioxide (CI 77891), Arnica Montana Flower Extract, Camellia Sinensis Leaf Extract, Cetyl Alcohol, Magnesium Aluminum Silicate, Cetareth-20, Laureth-7, PEG-100 Stearate, C13-14 Isoparaffin, Bisabolol, Glyceryl Stearate, Xanthan Gum, Fragrance/Parfum, Methylparaben, Glutaral, Chlorphenesin, Diazolidinyl Urea, Phenoxyethanol, Propylparaben, Citronellol, Geraniol, Limonene, Linalool, Violet 2 (CI 60725), Red 33 (CI 17200).

SOOTHE Sensitive Skin Treatment

50 mL/1.7 Fl.Oz.

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 Ocymoides 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).

REDEFINE Triple Defense Treatment SPF 30

30 mL/1.0 Fl.Oz.

Drug Facts

Active Ingredients

Avobenzone 3%

Homosalate 2.5%

Octisalate 5%

Octocrylene 2.7%

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:
 - at least every 2 hours
 - use a water-resistant sunscreen if swimming or sweating
- **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

Water/Aqua/Eau, Isododecane, Ethylhexyl Palmitate, Polymethylsilsesquioxane, Glycerin, Dimethicone, Cetyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Silica, Tetrapeptide-21, Dunaliella Salina Extract, Hydrolyzed Silk, Resveratrol, Sodium Hyaluronate, Humic Acids, Olea Europaea (Olive) Fruit Extract, Camellia Oleifera Leaf Extract, Talc, Sucrose Stearate, Polyurethane-40, Polysorbate 20, Polyisobutene, Polyacrylate-13, PEG-12 Dimethicone, Hydrogenated Polydecene, Fragrance/Parfum, Sorbitan Isostearate, Butylene Glycol, Caprylyl Glycol, Chlorphenesin, Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Propylparaben, Isobutylparaben, Iron Oxides (CI 77491, CI 77492).

Principal Display Panel –Carton

RODAN+FIELDS®

BEYONND THE SHAVE™

A smart approach to men's skincare to help relieve razor irritation and reveal better-looking skin.

This three-product Regimen was curated by Stanford-trained dermatologists Dr. Katie Rodan and Dr. Kathy Fields to address a man's specific shaving needs.

RODAN+FIELDS®

FOR MEN

SHAVE

UNBLEMISH™ Acne Treatment

Sulfur Wash

125 mL /

4.2 Fl. Oz

SOOTHE

SOOTHE™ Sensitive Skin

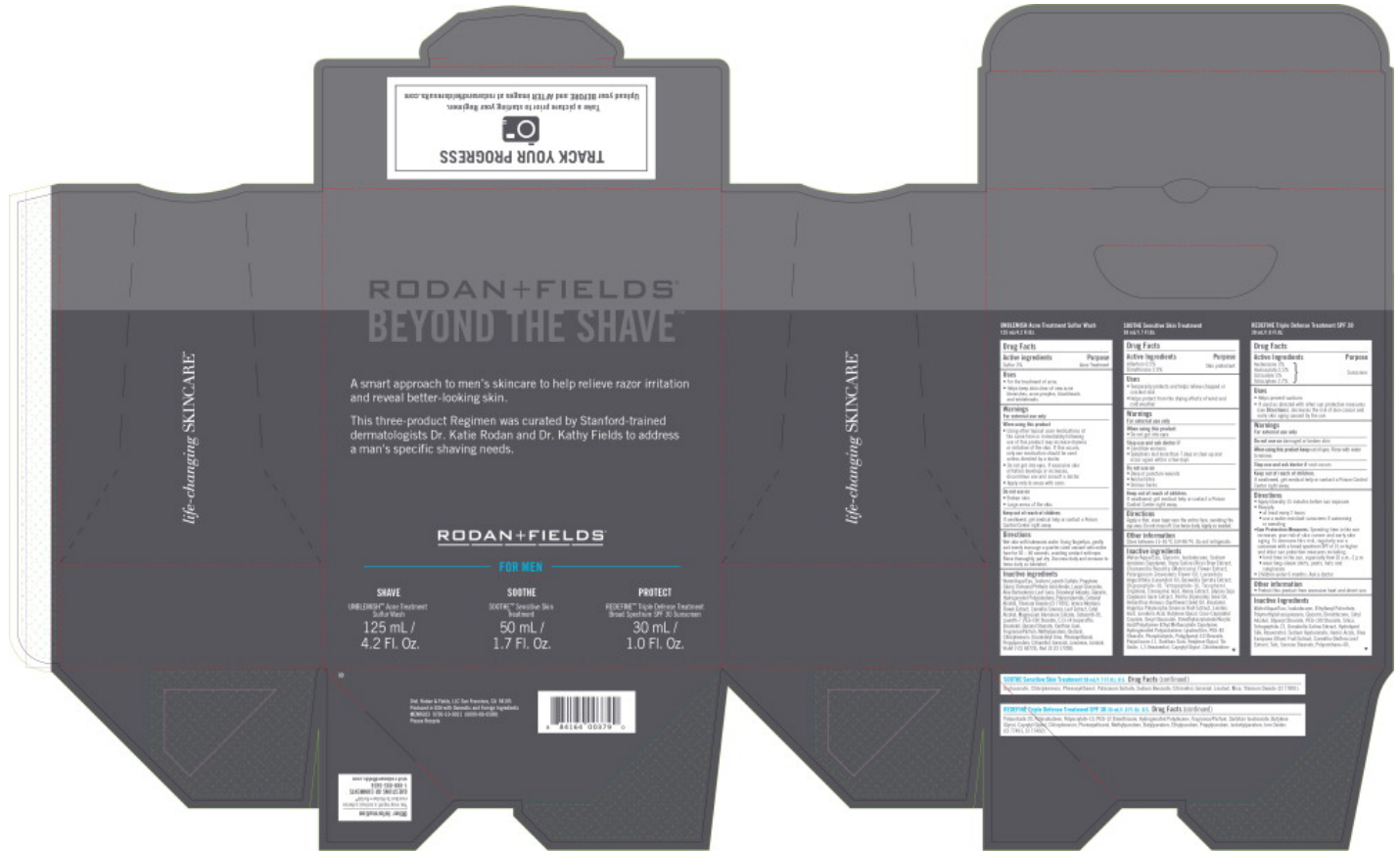
Treatment

50 mL /

1.7 Fl. Oz.

PROTECT

REDEFINE™ Triple Defense Treatment
 Broad Spectrum SPF 30 Sunscreen
 30 mL /
 1.7 Fl. Oz.



Principal Display Panel – Tube Label

RODAN+FIELDS®
 UNBLEMISHED

1

Acne Treatment

Sulfur Wash

RODAN+FIELDS®
UNBLEMISH

1

Acne Treatment
Sulfur Wash

P ores to
control acne blemishes.

DIRECTIONS: Wet skin with lukewarm water. Using fingertips, gently and evenly massage a quarter-sized amount onto entire face for 30–60 seconds, avoiding contact with eyes. Rinse thoroughly; pat dry. Use once daily and increase to twice daily as tolerated.

ACTIVE INGREDIENT: Sulfur 3%

WARNINGS: For external use only. Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. Do not get into eyes. If excessive skin irritation develops or increases discontinue use and consult a doctor. 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 UNWA125 85-07-0016 Please Recycle
visit rodanandfields.com

QUESTIONS OR COMMENTS 1-888-995-5656

125 mL/4.2 Fl.Oz.

Principal Display Panel – Tube

RODAN+FIELDS®
SOOTHE

2

Sensitive Skin Treatment

RODAN+FIELDS®
S O T T H E

2 Sensitive Skin Treatment

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.

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

WARNINGS: For external use only. When using this product, do not get into eyes. Stop use and ask doctor if condition worsens or 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.

Dist. Rodan & Fields, LLC
 San Francisco, CA 94105
 SOTT050 8500-06-0029
 Please Recycle (6000-06-5056)
 visit rodanandfields.com
QUESTIONS OR COMMENTS 1-888-995-5656
50 mL/1.7 Fl. Oz.

Principal Display Panel – Jar Label

RODAN+FIELDS®
 REDEFINE am

3

Triple Defense Treatment

BROAD SPECTRUM SPF 30

<p>RODAN+FIELDS® 3 REDEFINE am</p> <p>Triple Defense Treatment</p> <p>BROAD SPECTRUM SPF 30</p>	<p>PURPOSE: Helps defend against sun and environmental aggressors, while reducing the appearance of lines and wrinkles. DIRECTIONS: Every morning, after cleansing and toning, apply a dime-sized amount evenly over the entire face, avoid the eye area. ACTIVE INGREDIENTS: Avobenzone 3%, Homosalate 2.5%, Octisalate 5%, Octocrylene 2.7% – Sunscreen WARNINGS: For external use only. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately Manufactured for Rodan & Fields, LLC San Francisco, CA 94105 Made in USA AATT030 85-02-0045 Please Recycle visit rodanandfields.com QUESTIONS OR COMMENTS 1-888-995-5656</p> <p style="text-align: right;">30 mL/1 F</p>
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BEYOND THE SHAVE FOR MEN

sulfur, allantoin, dimethicone, avobenzone, homosalate, octisalate, octocrylene kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14222-6000
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-6000-1	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	125 mL
Part 2	1 TUBE	50 mL
Part 3	1 JAR	30 mL

Part 1 of 3**UNBLEMISH ACNE TREATMENT SULFUR WASH**

sulfur cream

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sulfur (UNII: 70FD1KFU70) (Sulfur - UNII:70FD1KFU70)	Sulfur	3.0 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Sodium Laureth Sulfate (UNII: BPV390UAP0)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Distearyl Phthalamic Acid (UNII: 5552GSZ9LI)	
Lauryl Glucoside (UNII: 76LN7P7UCU)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Diisodecyl Adipate (UNII: 3V0Q382O0P)	
Glycerin (UNII: PDC6A3C0OX)	
Hydrogenated Polybutene (1300 MW) (UNII: 7D1YQ9Y5EZ)	
Polyacrylamide (1500 MW) (UNII: 5D6TC4BRWV)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Arnica Montana Flower (UNII: OZ0E5Y15PZ)	

Green Tea Leaf (UNII: W2ZU1RY8B0)
Cetyl Alcohol (UNII: 936JST6JCN)
Magnesium Aluminum Silicate (UNII: 6M3P64V0NC)
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)
Laureth-7 (UNII: Z95S6G8201)
PEG-100 Stearate (UNII: YD01N1999R)
C13-14 Isoparaffin (UNII: E4F12ROE70)
Levomenol (UNII: 24WE03BX2T)
Glyceryl Monostearate (UNII: 230OU9XXE4)
Xanthan Gum (UNII: TTV12P4NEE)
Methylparaben (UNII: A2I8C7HI9T)
Glutaral (UNII: T3C89M417N)
Chlorphenesin (UNII: I670DAL4S2)
Diazolidinyl Urea (UNII: H5RIZ3MPW4)
Phenoxyethanol (UNII: HIE492ZZ3T)
Propylparaben (UNII: Z8IX2SC1OH)
.Beta.-Citronellol, (R)- (UNII: P01OUT964K)
Geraniol (UNII: L837108USY)
Limonene, (+)- (UNII: GFD7C86Q1W)
Linalool, (+/-)- (UNII: D81QY6I88E)
D&C Violet No. 2 (UNII: 350KA7O6HK)
D&C Red No. 33 (UNII: 9DBA0SBB0L)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		125 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	part333D	06/01/2017	

Part 2 of 3

SOOTHE SENSITIVE SKIN TREATMENT
allantoin, dimethicone lotion

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (Allanto in - UNII:344S277G0Z)	Allanto in	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: 1DE56QDM62)	
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 3 of 3

REDEFINE TRIPLE DEFENSE TREATMENT SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	3.0 g in 100 mL
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	2.5 g in 100 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	5 g in 100 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	2.7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Isododecane (UNII: A8289P68Y2)	
Ethylhexyl Palmitate (UNII: 2865993309)	
Polymethylsilsequioxane (11 Microns) (UNII: Z570VEV8XK)	
Glycerin (UNII: PDC6A3C0OX)	
Dimethicone (UNII: 92RU3N3Y1O)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Glyceryl Stearate SE (UNII: FCZ5MH785I)	
PEG-100 Stearate (UNII: YD01N1999R)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Tetrapeptide-21 (UNII: 179JUC43HU)	
Dunaliella Salina (UNII: F401DKI9A6)	
Bombyx Mori Fiber (UNII: 6LK42KUV6W)	
Resveratrol (UNII: Q369O8926L)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Black Olive (UNII: 2M6QWV94OC)	
Camellia Oleifera Leaf (UNII: 5077EL0C60)	

Talc (UNII: 7SEV7J4R1U)
Sucrose Stearate (UNII: 274KW0O50M)
Polysorbate 20 (UNII: 7T1F30V5YH)
Polyisobutylene (1000 MW) (UNII: 5XB3A63Y52)
PEG-12 Dimethicone (UNII: ZEL54N6W95)
Hydrogenated Polydecene (550 MW) (UNII: U333RI6EB7)
Sorbitan Isostearate (UNII: 01S2G2C1E4)
Butylene Glycol (UNII: 3XUS85K0RA)
Caprylyl Glycol (UNII: 00YIU5438U)
Chlorphenesin (UNII: I670DAL4SZ)
Phenoxyethanol (UNII: HIE492ZZ3T)
Methylparaben (UNII: A2I8C7HI9T)
Butylparaben (UNII: 3QP1I1U3FV8)
Ethylparaben (UNII: 14255EXE39)
Propylparaben (UNII: Z8IX2SC1OH)
Isobutylparaben (UNII: 0QQJ25X58G)
Ferrous Oxide (UNII: G7036X8B5H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 mL in 1 JAR; Type 0: Not a Combination Product		

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

Rodan & Fields