

## **RODAN AND FIELDS REDEFINE AM SPF 30- octisalate, avobenzone, octocrylene, homosalate cream**

### **Rodan and 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.*

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### **Rodan + Fields Redefine AM Cream**

#### **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 onyl**

⚠**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 a doctor** ⚠if rash occurs

⚠**Keep out of reach of children.** ⚠If product is swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Apply a dime-sized amount evenly over entire face every morning and 15 minutes before sun exposure, avoiding the eye area.
- Use a water resistant sunscreen if swimming or sweating
- Reapply 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.

## Inactive ingredients

Water, Isododecane, Ethylhexyl Palmitate, Polymethylsilsesquioxane, Glycerin, Dimethicone, Cetyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Butylene Glycol, Caprylyl Glycol, Sucrose Stearate, Olea Europaea (Olive) Fruit Extract, Hydrogenated Polydecene, Polyurethane-40, Hydrolyzed Silk, Fragrance, Silica, Camellia Oleifera Leaf Extract, Polyacrylate-13, Polyisobutene, Polysorbate-20, Iron Oxides, Tetrapeptide-21, Resveratrol, Phenoxyethanol, Chlorphenesin, Dunaliella Salina Extract, Talc, PEG-12 Dimethicone, Humic Acids, Sodium Hyaluronate

## Other Information

Protect this product from excessive heat and direct sun

❑ **QUESTIONS OR COMMENTS 1-888-995-5656**

Manufactured for Rodan and Fields, LLC

11 Maiden Lane, Suite 400

San Francisco, CA 94108

Made in USA



<p><b>Drug Facts (continued)</b></p> <p>water to remove.</p> <p><b>Stop use and ask a doctor</b> if rash occurs.</p> <p><b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>Apply a dime-sized amount evenly over entire face every morning and 15 minutes before sun exposure, avoiding the eye area.</li> <li>Use a water resistant sunscreen if swimming or sweating.</li> <li>Reapply at least every 2 hours.</li> <li><b>Sun Protection Measures.</b> 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</li> </ul>
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<p><b>Uses</b></p> <ul style="list-style-type: none"> <li>Helps prevent sunburn.</li> <li>If used as directed with other sun protection measures (see <b>Directions</b>), decreases the risk of skin cancer and early skin aging caused by the sun.</li> </ul>	
<p><b>Warnings For external use only.</b></p> <p><b>Do not use</b> on damaged or broken skin.</p> <p><b>When using this product</b> keep out of eyes. Rinse with</p>	



RODAN AND FIELDS REDEFINE AM SPF 30			
octisalate, avobenzene, octocrylene, homosalate cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14222-2250
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength

<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 g in 100 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 g in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.7 g in 100 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2.5 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCROSE STEARATE</b> (UNII: 274KW0O50M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>PEG-12 DIMETHICONE (300 CST)</b> (UNII: ZEL54N6W95)	
<b>CAMELLIA OLEIFERA LEAF</b> (UNII: 5077EL0C60)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>HYDROGENATED POLYDECENE (550 MW)</b> (UNII: U333RI6EB7)	
<b>DUNALIELLA SALINA</b> (UNII: F401DKI9A6)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>TETRAPEPTIDE-21</b> (UNII: 179JUC43HU)	
<b>BOMBYX MORI FIBER</b> (UNII: 6LK42KUV6W)	
<b>BLACK OLIVE</b> (UNII: 2M6QWV94OC)	
<b>PEG-9 DIGLYCIDYL ETHER/SODIUM HYALURONATE CROSSPOLYMER</b> (UNII: 788QAG3W8A)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>RESVERATROL</b> (UNII: Q369O8926L)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>POLYISOBUTYLENE (1000 MW)</b> (UNII: 5XB3A63Y52)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-2250-2	1 in 1 CARTON	05/01/2013	
1	NDC:14222-2250-1	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	05/01/2013	

