

## **SPOTLESS ACNE CLEARING TREATMENT- benzoyl peroxide 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.*

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### **Drug Facts**

#### **Active Ingredient**

Benzoyl Peroxide 2.5%

#### **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**

- Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

##### **Stop and ask a doctor**

- If skin irritation becomes severe.

##### **Do not use if you**

- Have very sensitive skin.
- Are sensitive to benzoyl peroxide.

##### **When using this product**

- Avoid unnecessary sun exposure and use a sunscreen.
- Avoid contact with the eyes, lips, and mouth.
- Avoid contact with hair and dyed fabrics, which may be bleached by this product.
- Skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.
- **Keep out of reach of children.** If swallowed get medical help or contact a Poison Control Center right away.

#### **Directions**

- Clean the skin thoroughly before applying this product.
- Dispense 1-2 pumps and cover the entire affected area with a thin even layer one to three times daily. Do not rinse product off face.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.

- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.
- Wash hands after application to help avoid staining fabrics.

### **Other Information**

Store between 15-30°C (59-86°F). This product may bleach hair or dyed fabrics.

### **Inactive Ingredients**

Water, Glycereth-18 Ethylhexanoate, Glycereth-18, Glycerin, Butylene Glycol, Vaccinium Angustifolium (Blueberry) Fruit Extract, Sodium Hyaluronate, Polygonum Cuspidatum Root Extract, Bisabolol, Allantoin, Zingiber Officinale (Ginger) Root Extract, Octenidine HCL, Fragrance, Phytosteryl/Octyldodecyl Lauroyl Glutamate, Methyl Methacrylate Crosspolymer, Myristyl Alcohol, Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, Cyclopentasiloxane, Butyl Hydroxycyclohexane Carboxylate, Dimethyl Isosorbide, Carbomer, Polyglyceryl-2 Isostearate, Sorbitan Oleate, Diethylhexyl Sodium Sulfosuccinate, Cetyl Hydroxyethylcellulose, Cyclohexasiloxane, Polysorbate 80, Xanthan Gum, Hydroxyphenyl Propamidobenzoic Acid, Ascorbyl Palmitate, Tocopherol, PCA, Sodium Citrate, Citric Acid, Sodium Hydroxide, Propanediol, Pentylene Glycol, Isohexadecane, Caprylyl Glycol, 1,2-Hexanediol, Decylene Glycol, Hydroxyacetophenone, Propylene Glycol, Ethylhexylglycerin, Hexylene Glycol, Phenoxyethanol, Citral, Citronellol, Limonene, Linalool, Titanium Dioxide (CI 77891), Mica, Tin Oxide, Blue 1 (CI 42090), Red 33 (CI 17200), Violet 2 (CI 60725)

### **Questions**

1-888-995-5656

### **Principal Display Panel - 50 mL Carton Label**

**RODAN+FIELDS**

**SPOTLESS**

**ACNE**

**CLEARING**

**TREATMENT**

**2**

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



**Principal Display Panel - 50 mL Tube Label**

**RODAN+FIELDS**

**SPOTLESS**

**ACNE**

**CLEARING**

**TREATMENT**

**2**

# RODDAN+FIELDS SPOTLESS

**Active Ingredient:**

Benzoyl Peroxide 2.5%

**Use:** For the treatment of acne.

**Directions:** Clean the skin thoroughly before applying this product. Apply a thin layer onto the face one to two times daily. Start with one application daily, then gradually increase to two times if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day. If going outside, apply sunscreen after using this product.

**Warnings: For external use only.**

When using this product skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one at a time. Avoid unnecessary sun exposure and use a sunscreen. Avoid contact with the eyes, lips, and mouth. Avoid contact with hair and dyed fabrics, which may be bleached by this product. Skin irritation may occur, and may be reduced by using the product less frequently. Do not use if you have very sensitive skin, or are sensitive to Benzoyl Peroxide. Stop use and ask a doctor if irritation becomes severe. Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

**ACNE  
CLEARING  
TREATMENT**

**2**

rodanandfields.com

Questions 1-888-995-5656

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

UNST030 8500-07-0028  
(6099-07-0002) 0A

50 mL / 1.7 fl. oz.

## SPOTLESS ACNE CLEARING TREATMENT

benzoyl peroxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14222-1620
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	0.025 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERETH-18 ETHYLHEXANOATE</b> (UNII: IWS58C6V2Y)	
<b>GLYCERETH-18</b> (UNII: SA5E43C17C)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
<b>CETYL HYDROXYETHYLCELLULOSE (350000 MW)</b> (UNII: T7SWE4S2TT)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PC10R)	
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	

<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)
<b>D&amp;C VIOLET NO. 2</b> (UNII: 350KA7O6HK)
<b>DECYLENE GLYCOL</b> (UNII: S57M60MI88)
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)
<b>GINGER</b> (UNII: C5529G5JPQ)
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)
<b>HYDROXYPHENYL PROPAMIDOBENZOIC ACID</b> (UNII: 25KRT26H77)
<b>ISOHEXADECANE</b> (UNII: 918X10UF1E)
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)
<b>LOWBUSH BLUEBERRY</b> (UNII: G90PX41VP0)
<b>METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: 657L0NC5MT)
<b>MICA</b> (UNII: V8A1AW0880)
<b>MYRISTYL ALCOHOL</b> (UNII: V42034O9PU)
<b>OCTENIDINE HYDROCHLORIDE</b> (UNII: U84956NU4B)
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE</b> (UNII: 65954KGO9Q)
<b>PIDOLIC ACID</b> (UNII: SZB83O1W42)
<b>POLYGLYCERYL-2 MONOISOSTEARATE</b> (UNII: 7B8OE71MQC)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>REYNOUTRIA JAPONICA ROOT</b> (UNII: 7TRV45YZF7)
<b>SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MP.A.S)</b> (UNII: 5F4963KLHS)
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>SORBITAN MONOLEATE</b> (UNII: 06XEA2VD56)
<b>STANNIC OXIDE</b> (UNII: KM7N50LOS6)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-1620-1	1 in 1 CARTON	02/13/2019	
1		50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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**Labeler** - Rodan & Fields (051659584)

Revised: 2/2019

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