

## **UNBLEMISH- benzoyl peroxide lotion**

**Rodan & Fields, LLC**

*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 Unblemish**

#### **Drug Facts**

##### **Active ingredient**

Benzoyl Peroxide 5%

##### **Purpose**

Acne treatment

##### **Uses**

- For the treatment of acne.
- Penetrates pores to control acne blemishes, pimples and blackheads.
- Helps prevent new acne blemishes, pimples and blackheads from forming.

##### **Warnings**

**☐For external use only.**

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

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

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

- Skin irritation and dryness are 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.
- 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 combination.

**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.

##### **Directions**

- Cleanse skin thoroughly before applying this product.
- Dispense 1-2 pumps from each side. Blend product and apply evenly over the entire face, avoiding

the eye area. Allow to penetrate skin. Do not rinse off.

- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to twice daily as needed or as directed by a doctor. If bothersome dryness or peeling occur reduce application to once a day or every other day and apply a moisturizer.
- If going outside, apply sunscreen after using this product. If irritation or sensitivity develop, stop use of both products and ask a doctor.

### Other information

You may report a serious adverse reaction to Rodan+Fields® , Attn: Product Development, 60 Spear Street, Suite 600, San Francisco, CA 94105.

### Inactive ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Biosaccharide Gum-1, Carbomer, C13-14 Isoparaffin, Ceramide AP, Ceramide EOP, Ceramide NP, Chamomilla Recutita (Matricaria) Flower Extract, Cholesterol, Disodium EDTA, Disodium Oleamido MEA Sulfosuccinate, Glycerin, Laureth-7, Niacinamide, Panthenol, Phytosphingosine, Polyacrylamide, Punica Granatum Extract, Purified Water, Sodium Lauroyl Lactylate, Xanthan Gum, Yucca Glauca Root Extract

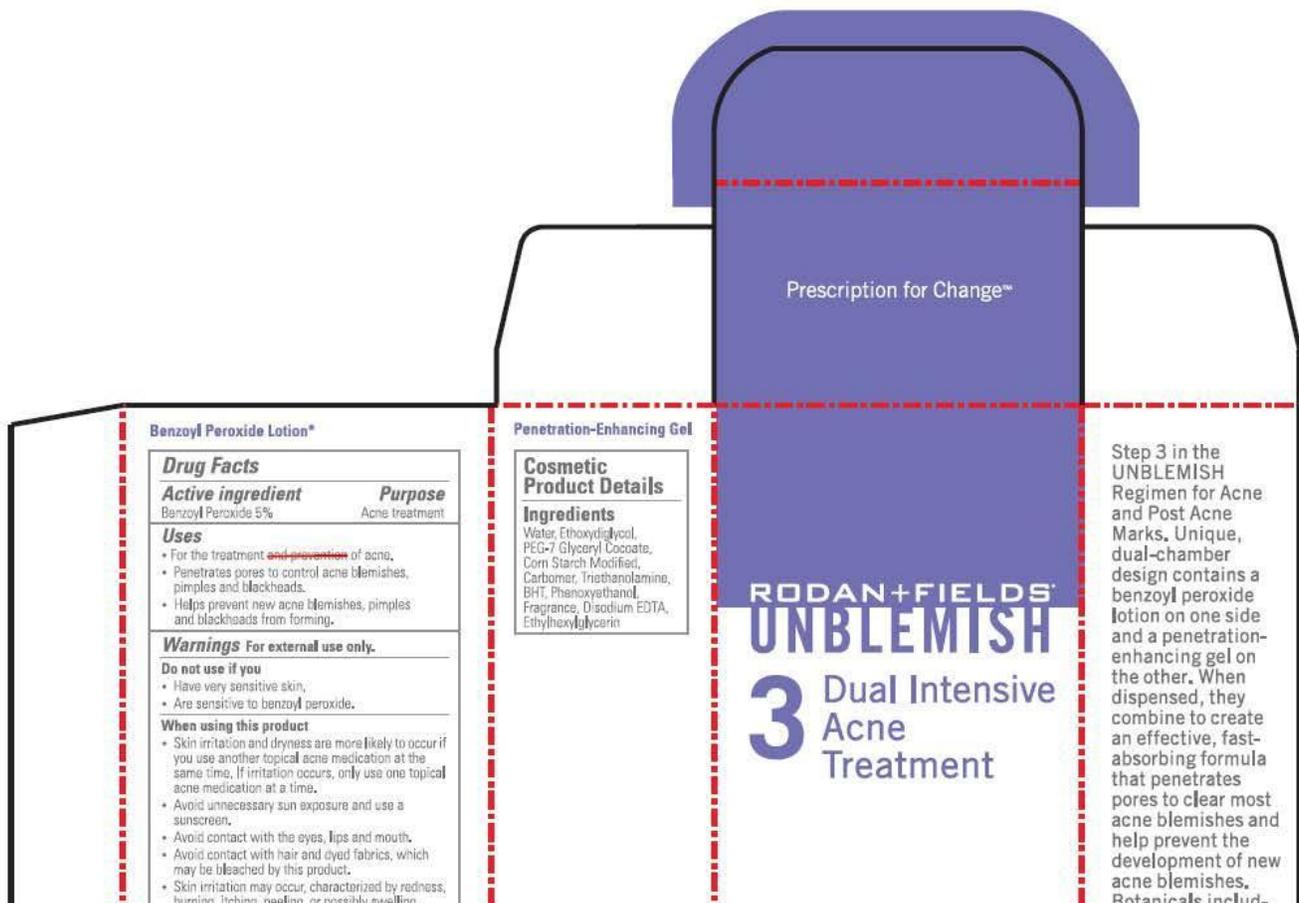
### Principal Display Panel - Rodan+Fields

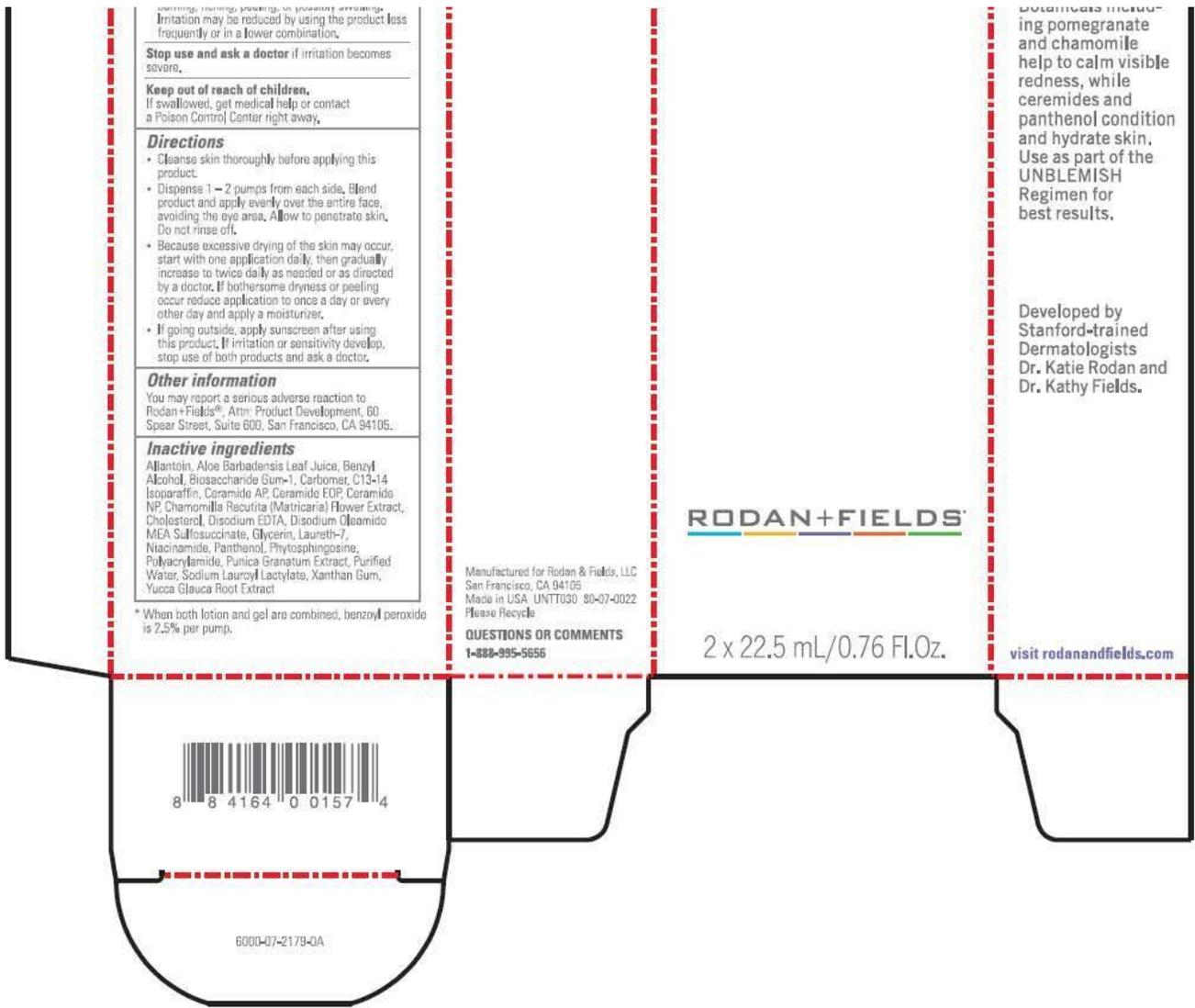
Rodan+Fields

Unblemish

Dual Intensive Acne Treatment

2 X 22.5 mL/0.76 Fl. Oz.





## UNBLEMISH

benzoyl peroxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14222-2000
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)
<b>BIO SACCHARIDE GUM-1</b> (UNII: BB4PU4V09H)
<b>CARBOMER 934</b> (UNII: Z135WT9208)
<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)
<b>CERAMIDE 6 II</b> (UNII: F1X8L2B00J)
<b>CERAMIDE 1</b> (UNII: 5THT33P7X7)
<b>CERAMIDE 3</b> (UNII: 4370DF050B)
<b>CHAMOMILE</b> (UNII: FGL3685T2X)
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>DISODIUM OLEAMIDO MEA-SULFO SUCCINATE</b> (UNII: 5M1101WGSY)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>LAURETH-7</b> (UNII: Z95S6G8201)
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)
<b>PHYTOSPHINGOSINE</b> (UNII: GIN46U9Q2Q)
<b>SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPa.S)</b> (UNII: 5F4963KLHS)
<b>PUNICA GRANATUM ROOT BARK</b> (UNII: CLV24I3T1D)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SODIUM LAUROYL LACTYLATE</b> (UNII: 7243K85WFO)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>YUCCA GLAUCA ROOT</b> (UNII: 1A15YBH7N1)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-2000-2	1 in 1 CARTON		
1		22.5 mL in 1 BOTTLE, PUMP		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	06/01/2014	

**Labeler** - Rodan & Fields, LLC (051659584)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Ei LLC		105803274	manufacture(14222-2000) , analysis(14222-2000) , label(14222-2000)