

SPOTLESS REGIMEN FOR ACNE, BLEMISHES AND BREAKOUTS- benzoyl peroxide 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.

Daily Acne Wash

Drug Facts

Active Ingredient

Benzoyl Peroxide 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.

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.

Stop and ask a doctor if

- Skin irritation becomes severe.

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, apply a thin, even layer and massage over entire face for 90 seconds, avoiding all contact with eyes. Rinse thoroughly and pat dry. Use once daily and increase to twice daily as tolerated. Wash hands after application to help avoid staining fabrics.
- 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.

Other Information

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

Inactive Ingredients

Water, Polyacrylamide, C13-14 Isoalkane, Jojoba Esters, Carbomer, Diethylhexyl Sodium Sulfosuccinate, Cocamidopropyl Betaine, Laureth-7, Sodium Chloride, Sodium Citrate, Sodium Hydroxide, Propanediol, Ethylhexylglycerin, Phenoxyethanol, Sodium Benzoate.

Questions? 1-888-995-5656

Acne Clearing Treatment

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.

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.

Stop and ask a doctor if

- Skin irritation becomes severe.

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, Disiloxane, Glycerin, Butylene Glycol, Propanediol, Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, Allantoin, Ascorbyl Palmitate, Bisabolol, Myristyl Alcohol, PCA, Phytosteryl/Octyldodecyl Lauroyl Glutamate, Polygonum Cuspidatum Root Extract, Sodium Hyaluronate, Vaccinium Angustifolium (Blueberry) Fruit Extract, Zingiber Officinale (Ginger) Root Extract, Fragrance/Parfum, Carbomer, Methyl Methacrylate Crosspolymer, Cetyl Hydroxyethylcellulose,

Hydroxyphenyl Propamidobenzoic Acid, Polyglyceryl-2 Isostearate, Polysorbate 80, Sorbitan Oleate, Xanthan Gum, Diethylhexyl Sodium Sulfosuccinate, Isohexadecane, Dimethyl Isosorbide, Tocopherol, Citric Acid, Sodium Citrate, Sodium Hydroxide, Caprylyl Glycol, Decylene Glycol, Hexylene Glycol, Pentylene Glycol, 1,2-Hexanediol, Ethylhexylglycerin, Hydroxyacetophenone, Phenoxyethanol, Citral, Citronellol, Limonene, Linalool, Mica, Tin Oxide, Titanium Dioxide, Blue 1 (CI 42090), Ext. Violet 2 (CI 60730), Red 33 (CI 17200).

Questions? 1-888-995-5656

*When both lotion and gel are combined equally, Benzoyl Peroxide is 2.5%

Principal Display Panel - Kit Label

RODAN+FIELDS

SPOTLESS

**REGIMEN FOR
ACNE, BLEMISHES
AND BREAKOUTS**

**DESIGNED FOR
TEENS AND YOUNG ADULTS**

- **Eliminates acne-causing bacteria**
- **Helps clear blackheads, whiteheads and pimples**
- **Helps prevent new blemishes from forming**
- **Reduces shine**

**DEVELOPED BY STANFORD-TRAINED
DERMATOLOGISTS DR.KATIE RODAN
AND DR.KATHY FIELDS**

Daily Acne Wash

Benzoyl Peroxide Cream

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

Acne Clearing Treatment

Benzoyl Peroxide Lotion*

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



Principal Display Panel - Acne Clearing Treatment 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.

Principal Display Panel - Daily Acne Wash Tube Label

RODAN+FIELDS

SPOTLESS

**DAILY
ACNE
WASH**

1

RODDAN+FIELDS SPOTLESS

Active Ingredient: Benzoyl Peroxide 5%

Use: For the treatment of acne.

Directions: Wet face. Apply to hands, lather and massage onto the face gently. Rinse thoroughly after 90 seconds. Start with one application daily, then gradually increase to two times, if needed. If 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 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 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.

**DAILY
ACNE
WASH**

1

rodanandfields.com

Questions 1-888-995-5656

Dist. Rodan & Fields, LLC

San Francisco, CA 94105

UNSW125 8500-07-0027

(6000-07-5056) OA

125 mL / 4.2 fl. oz.

SPOTLESS REGIMEN FOR ACNE, BLEMISHES AND BREAKOUTS

benzoyl peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14222-1600
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-1600-1	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	02/13/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	125 mL
Part 2	1 BOTTLE, PUMP	50 mL

Part 1 of 2

SPOTLESS DAILY ACNE WASH

benzoyl peroxide cream

Product Information

Item Code (Source)	NDC:14222-1610
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	0.05 g in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
LAURETH-7 (UNII: Z95S6G8201)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPANEDIOL (UNII: 5965N8W85T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-1610-1	1 in 1 CARTON		
1		125 mL in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/13/2019	

Part 2 of 2

SPOTLESS ACNE CLEARING TREATMENT

benzoyl peroxide lotion

Product Information

Item Code (Source)	NDC:14222-1620
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERETH-18 ETHYLHEXANOATE (UNII: IWS58C6V2Y)	
GLYCERETH-18 (UNII: SA5E43C17C)	
HEXAMETHYLDISILOXANE (UNII: D7M4659BPU)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PROPANEDIOL (UNII: 5965N8W85T)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ALLANTOIN (UNII: 344S277G0Z)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
Ext. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	
DECYLENE GLYCOL (UNII: S57M60MI88)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GINGER (UNII: C5529G5JPQ)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
HYDROXYPHENYL PROPAMIDOBENZOIC ACID (UNII: 25KRT26H77)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
LEVOMENOL (UNII: 24WE03BX2T)	
LOWBUSH BLUEBERRY (UNII: G90PX41VP0)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
MICA (UNII: V8A1AW0880)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
PIDOLIC ACID (UNII: SZB83O1W42)	
POLYGLYCERYL-2 ISOSTEARATE (UNII: 7B8OE71MQC)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
REYNOUtria JAPONICA ROOT (UNII: 7TRV45YZF7)	
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-1620-1	1 in 1 CARTON		
1		50 mL in 1 BOTTLE, PUMP; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/13/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/13/2019	

Labeler - Rodan & Fields (051659584)