

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.

Drug Facts

Active Ingredient

Benzoyl Peroxide 2.5% Acne

Purpose

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 - 50 mL Carton Label

RODAN+FIELDS

SPOTLESS

ACNE

CLEARING

TREATMENT

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

R+F

Benzoyl Peroxide Lotion*

Drug Facts

Active Ingredient	Purpose
Benzoyl Peroxide 2.5%	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, ▶

Drug Facts (continued)

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%



Dist. Rodan & Fields, LLC
San Ramon, CA 94583
Made in USA with US and Imported Materials
(6000-13-0013) OA
Please Recycle

Step 2 in the SPOTLESS Regimen for Acne, Blemishes and Breakouts specifically designed for teens and young adults

ACNE CLEARING TREATMENT IS A LIGHTWEIGHT LOTION DESIGNED TO:

- Penetrate pores to clear most blackheads, whiteheads and pimples
- Reduce the number and severity of blemishes, while allowing skin to heal
- Help prevent future breakouts

For best results, use with SPOTLESS Daily Acne Wash

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

life-changing SKINCARE

rodanandfields.com

RODAN+FIELDS
SPOTLESS

ACNE
CLEARING
TREATMENT

2

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

KNOCK OUT AREA
FOR LOT CODE -
DOES NOT PRINT



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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	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: 3XUS85KORA)	
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: 9DBA05BB0L)
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	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
OTC monograph final	part333D	02/13/2019	

