SPOTLESS DAILY ACNE WASH- benzoyl peroxide cream 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 Ingredients

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

• 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 Isoparaffin, Jojoba Esters, Carbomer, Diethylhexyl Sodium Sulfosuccinate, Cocamidopropyl Betaine, Laureth-7, Sodium Chloride, Sodium Citrate, Sodium Hydroxide, Propanediol, Ethylhexylglycerin, Phenoxyethanol, Sodium Benzoate

Questions

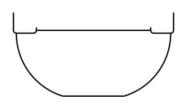
1-888-995-5656

Principal Display Panel - 125 mL Carton Label RODAN+FIELDS SPOTLESS DAILY ACNE WASH

1

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





Principal Display Panel - 125 mL Tube Label

RODAN+FIELDS

SPOTLESS

DAILY

ACNE

WASH

1

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.



Questions 1-888-995-5656

Dist. Rodan & Fields, LLC San Francisco, CA 94105 UNSW125 8500-07-0027 (6000-07-5056) 0A

125 mL / 4.2 fl. oz.

SPOTLESS DAILY ACNE WASH

benzoyl peroxide cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:14222-1610

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM) BENZOYL PEROXIDE | 0.05 g in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)				
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11 KX)				
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)				
SO DIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)				

ı	P	Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1	NDC:14222-1610-1	1 in 1 CARTON	02/13/2019			

1	25 mL in 1 TUBE; 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	0 2/13/20 19					

Labeler - Rodan & Fields (051659584)

Revised: 2/2019 Rodan & Fields