

PROACTIVPLUS SKIN SMOOTHING EXFOLIATOR- benzoyl peroxide lotion
Guthy-Renker 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.

Proactiv+ Skin Smoothing Exfoliator

Drug Facts

Active ingredient

Benzoyl peroxide 2.5%

Purpose

Acne treatment gel

Use

for the management of acne.

Warnings

For external use only

When using this product

- do not use this product more than three times per day.
- 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 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.

Do not use if you

- have very sensitive skin
- 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.

Directions

- *Sensitivity Test for a New User:* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.
- apply a small amount to dampened skin.
- cover the entire affected area with a thin layer and rinse thoroughly one to three times daily.

- 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.

Inactive ingredients

water, sodium cocoyl isethionate, glycerin, polyethylene, lauryl/myristyl benzoate, linoleic acid, linolenic acid, butylene glycol, dimethicone, ethylhexylglycerin, acrylates/C10-30 alkyl acrylate crosspolymer, glycolic acid, sodium hydroxide, phenoxyethanol, fragrance.

Questions or comments?

Within US **1-800-950-4695**

Dist. by: Guthy-Renker® LLC • PO Box 14383
Palm Desert, CA 92255-4383

PRINCIPAL DISPLAY PANEL - 60 mL Tube Box

Rodan & Fields

proactiv⁺

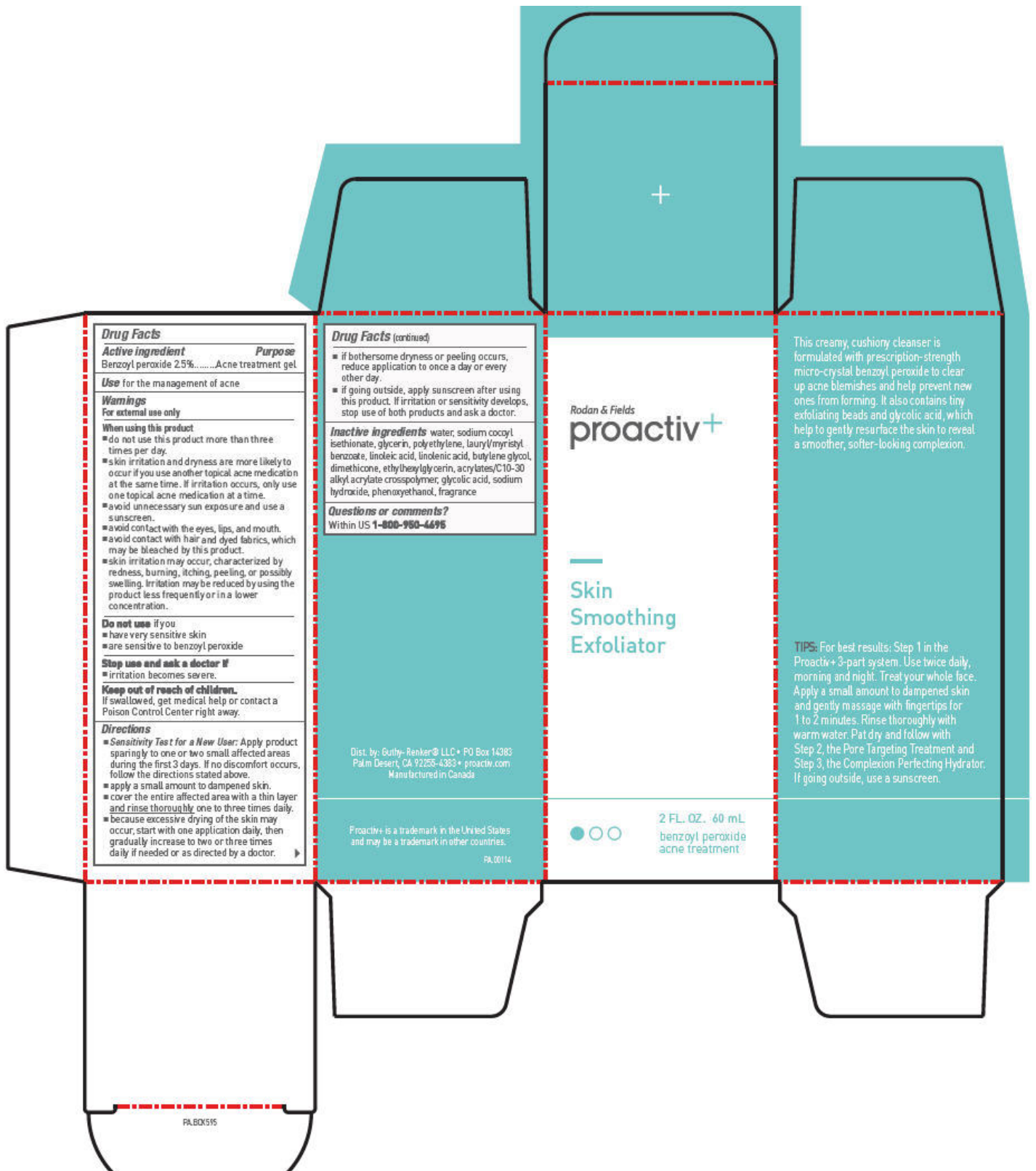
Skin

Smoothing

Exfoliator

2 FL. OZ. 60 mL

benzoyl peroxide
acne treatment



PROACTIVPLUS SKIN SMOOTHING EXFOLIATOR

benzoyl peroxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11410-011

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	2.5 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
LAURYL/MYRISTYL BENZOATE (UNII: N5RS934G6D)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
LINOLENIC ACID (UNII: 0RBV727H71)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-011-68	1 in 1 BOX	01/25/2013	
1		177.4 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11410-011-22	1 in 1 BOX	01/25/2013	
2		60 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	01/25/2013	

Labeler - Guthy-Renker LLC (608315453)