

PROACTIV RENEWING CLEANSER- benzoyl peroxide gel
Alchemee, LLC

Proactiv ®Renewing Cleanser

Drug Facts

Active ingredient

Benzoyl peroxide 2.5%

Purpose

Acne treatment

Use

for the management of acne

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, 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 below.

- 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, magnesium aluminum silicate, glyceryl stearate, PEG-100 stearate, sorbitol, dimethyl isosorbide, disodium PEG-12 dimethicone sulfosuccinate, tridecyl stearate, neopentyl glycol dicaprylate/dicaprate, paraffin, cetyl esters, tridecyl trimellitate, trisodium sulfosuccinate, PEG-12 dimethicone, xanthan gum, imidazolidinyl urea, fragrance, methylparaben, sodium sulfate, propylparaben, sodium PCA, propylene glycol, anthemis nobilis flower extract, phenoxyethanol, sodium hyaluronate

Questions or comments?

1-800-950-4695

Distributed by Alchemee LLC

Santa Monica, CA 90401

Made in the USA of Foreign

and Domestic Components

Questions? 1-800-950-4695 • proactiv.com

Proactiv is a registered trademark
of Taro Pharmaceuticals U.S.A., Inc.

PRINCIPAL DISPLAY PANEL - 120 mL CARTON

proactiv®

CLEANSE

1

RENEWING

CLEANSER

4 FL. OZ. (120 mL)

benzoyl peroxide acne medication

<p>Drug Facts</p> <p>Active ingredient Purpose Benzoyl peroxide 2.5%Acne treatment</p> <p>Use for the management of acne</p> <p>Warnings For external use only</p> <p>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, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.</p> <p>Do not use if you ■ have very sensitive skin ■ are sensitive to benzoyl peroxide</p> <p>Stop use and ask a doctor if ■ irritation becomes severe</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions <i>Sensitivity Test for a New User.</i> Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below. ■ cover the entire affected area with a thin layer and <u>rinse thoroughly</u> 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.</p>	<p>Drug Facts (continued)</p> <p>Inactive ingredients water, magnesium aluminum silicate, glyceryl stearate, PEG-100 stearate, sorbitol, dimethyl isosorbide, disodium PEG-12 dimethicone sulfosuccinate, tridecyl stearate, neopentyl glycol dicaprylate/dicaprate, paraffin, cetyl esters, tridecyl trimellitate, trisodium sulfosuccinate, PEG-12 dimethicone, xanthan gum, imidazolidinyl urea, fragrance, methylparaben, sodium sulfate, propylparaben, sodium PCA, propylene glycol, anthemis nobilis flower extract, phenoxethanol, sodium hyaluronate</p> <p>Questions or comments? 1-800-950-4695</p>	<p>proactiv.</p> <p>1 CLEANSE RENEWING CLEANSER</p> <p>4 FL. OZ. (120 mL)</p>		<p>This acne-fighting cleanser washes away excess oil, dirt and other impurities. It removes dead skin cells with tiny, smooth exfoliating beads. Micronized benzoyl peroxide is designed to quickly penetrate deep into pores to start to kill acne-causing bacteria on contact.</p>
<p>Distributed by Alchemee LLC Santa Monica, CA 90401 Made in the USA of Foreign and Domestic Components Questions? 1-800-950-4695 • proactiv.com</p>	<p>Proactiv is a registered trademark of Taro Pharmaceuticals U.S.A., Inc.</p> <p>benzoyl peroxide acne medication</p>			

PROACTIV RENEWING CLEANSER

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11410-005
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	2.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-100 STEARATE (UNII: YD01N1999R)
SORBITOL (UNII: 506T60A25R)
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)
TRIDECYL STEARATE (UNII: A8OE252M6L)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
PARAFFIN (UNII: I9O0E3H2ZE)
CETYL ESTERS WAX (UNII: D072FFP9GU)
CHAMAEMELUM NOBILE (UNII: 7NF3GE7IWR)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
TRISODIUM SULFOSUCCINATE (UNII: 085WB9L09N)
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
XANTHAN GUM (UNII: TTV12P4NEE)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-005-00	1 in 1 CARTON	03/07/2017	
1		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:11410-005-05	1 in 1 CARTON	03/07/2017	
2		120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:11410-005-40	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/21/2011	
4	NDC:11410-005-20	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2019	
5	NDC:11410-005-10	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/21/2011	
6	NDC:11410-005-70	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/21/2011	
7	NDC:11410-005-80	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/21/2011	
8	NDC:11410-005-01	1 in 1 CARTON	03/07/2017	
8		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:11410-005-75	1 in 1 CARTON	01/01/2020	
9		177 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	10/21/2011	

Labeler - Alchemee, LLC (080216357)

Establishment

Name	Address	ID/FEI	Business Operations
VEE PAK, LLC		874763303	manufacture(11410-005)

Establishment

Name	Address	ID/FEI	Business Operations
kdc/one Chatsworth, Inc.		118542196	manufacture(11410-005)

Revised: 11/2023

Alchemee, LLC