PR BENZOYL PEROXIDE WASH - benzoyl peroxide wash lotion
PruGen, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

PRTM Benzoyl Peroxide Wash Rev.1.4

DESCRIPTION:
PR^{TM} Benzoyl Peroxide Wash is intended for topical administration and contains Benzoyl Peroxide for use in the treatment of acne vulgaris. Benzoyl Peroxide is an oxidizing agent that possesses antibacterial properties and is classified s a keratolytic. Benzoyl Peroxide ($C_{14}H_{10}O_4$) is represented by the following chemical structure:
O = C – O – O – C = O

Each mL of PR^{TM} Benzoyl Peroxide Wash contains 70 mg of Benzoyl Peroxide in an emulsion based formulation consisting of: aloe, carbomer 940, cetyl alcohol, disodium oleamido MEA-sulfosuccinate, disodium EDTA, glyceryl stearate/PEG-100 stearate, glycerin, green tea, laureth-12, magnesium aluminum silicate, propylene glycol, purified water, sodium coco-sulfate, sodium lauroamphoacetate, xanthan gum.

CLINICAL PHARMACOLOGY:
The mechanism of action of Benzoyl Peroxide is not totally understood but its antibacterial activity against Propionibacterium acnes is thought to be a major mode of action. In addition, patients treated with Benzoyl Peroxide show a reduction in lipids and free fatty acids, and mild desquamation (drying and peeling activity) with simultaneous reduction in comedones and acne lesions. Little is known about the percutaneous penetration, metabolism, and excretion of Benzoyl Peroxide, although it has been shown that Benzoyl Peroxide absorbed by the skin is metabolized to benzoic acid and then excreted as benzoate in the urine. There is no evidence of systemic toxicity caused by Benzoyl Peroxide in humans.

INDICATIONS AND USAGE:
PR^{TM} Benzoyl Peroxide Wash is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS:
PR^{TM} Benzoyl Peroxide Wash is contraindicated in persons with a known hypersensitivity to any of its ingredients.

WARNINGS:
When using this product, avoid unnecessary sun exposure and use a sunscreen.
PRECAUTIONS:
General: For external use only. If severe irritation develops, discontinue use and institute appropriate therapy. After reaction clears, treatment may often be resumed with less frequent application. These preparations should not be used in or near the eyes or on mucous membranes.

Information For Patients:
Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. Contact with any colored material (including hair and fabric) may result in bleaching or discoloration. If excessive irritation develops, discontinue use and consult your physician.

Carcinogensesis, Mutagenesis, Impairment of Fertility:
Data from several studies employing a strain of mice that is highly susceptible to developing cancer suggest that Benzoyl Peroxide acts as a tumor promoter. The clinical significance of these findings to humans is unknown. Benzoyl Peroxide has not been found to be mutagenic (Ames Test) and there are no published data indicating it impairs fertility.

Pregnancy: Teratogenic Effects:
Pregnancy Category C: Animal reproduction studies have not been conducted with Benzoyl Peroxide. It

is not known whether Benzoyl Peroxide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzoyl Peroxide should be used by a pregnant woman only if clearly needed. There are no available data on the effect of Benzoyl Peroxide on the later growth, development and functional maturation of the unborn child.

ADVERSE REACTIONS:
Allergic contact dermatitis and dryness have been reported with topical Benzoyl Peroxide therapy.

OVERDOSAGE:
If excessive scaling, erythema or edema occurs, the use of this preparation should be discontinued. To hasten resolution of the adverse effects, cool compresses may be used. After symptoms and signs subside, a reduced dosage schedule may be cautiously tried if the reaction is judged to be due to excessive use and not allergenicity.

DOSAGE AND ADMINISTRATION:
PR™ Benzoyl Peroxide Wash: Apply to affected areas once or twice a day, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10-20 seconds, working into a full lather. Rinse thoroughly and pat dry. If excessive drying occurs, control by rinsing of cleanser sooner or using less often.

HOW SUPPLIED:
PR™ Benzoyl Peroxide Wash is supplied in a 16 oz bottle, NDC 42546-145-16.

Store at controlled room temperature 20°-25° C (68°-77° F); excursions permitted to 15°-30°C (59°-86°F).
Protect from freezing.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Box

NDC 42546-145-16

PR™
Benzoyl Peroxide
Wash (7% Benzoyl Peroxide)

TOPICAL ACNE THERAPY

7%

Rx only
Net wt. 16 oz

PRUGEN™
PHARMACEUTICALS

NDC 42546-145-16

PR™ Benzoyl Peroxide Wash (7% Benzoyl Peroxide)

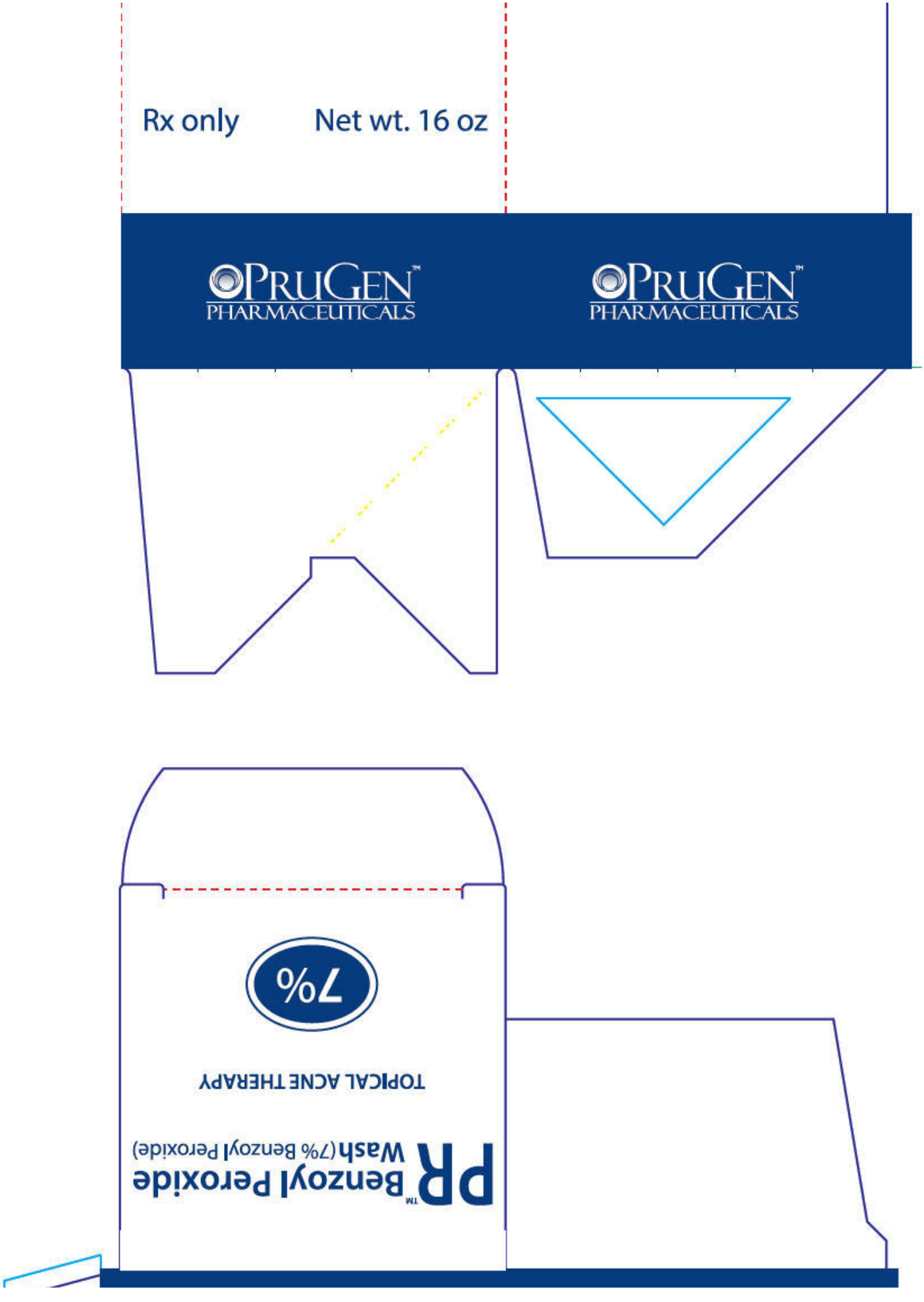
TOPICAL ACNE THERAPY

7%

PR™ Benzoyl Peroxide Wash (7% Benzoyl Peroxide)

TOPICAL ACNE THERAPY

7%


Rx only
Net wt. 16 oz
PRUGEN PHARMACEUTICALS
PRUGEN PHARMACEUTICALS
7%
TOPICAL ACNE THERAPY
PR Benzoyl Peroxide Wash (7% Benzoyl Peroxide)

SHAKE WELL

Drug Facts

Active ingredient (in each mL) — **Purpose**
Benzoyl Peroxide 70 mg ..... keratolytic

Uses indicated for the topical treatment of acne vulgaris

Warnings
For external use only

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 use and ask a doctor if
- irritation becomes severe

Keep out of reach of children

Directions
Apply **PR™ Benzoyl Peroxide Wash** to affected areas once or twice a day, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10–20 seconds, working into a full lather. Rinse thoroughly and pat dry. If excessive drying occurs, control by rinsing off cleanser sooner or using less often. See package insert for full prescribing information. 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 at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F)
- shake well / protect from freezing

Inactive ingredients
aloe, carbomer 940, cetyl alcohol, disodium oleamido MEA-sulfosuccinate, disodium EDTA, glyceryl stearate/PEG-100 stearate, glycerin, green tea, laureth-12, magnesium aluminum silicate, propylene glycol, purified water, sodium coco-sulfate, sodium lauroamphoacetate, xanthan gum.

Questions? 866-696-8525

Rev 3.0

Manufactured for:
PruGen Pharmaceuticals
18899 N Thompson Peak Pkwy
Scottsdale, AZ 85255

N 3 42546 14516 7

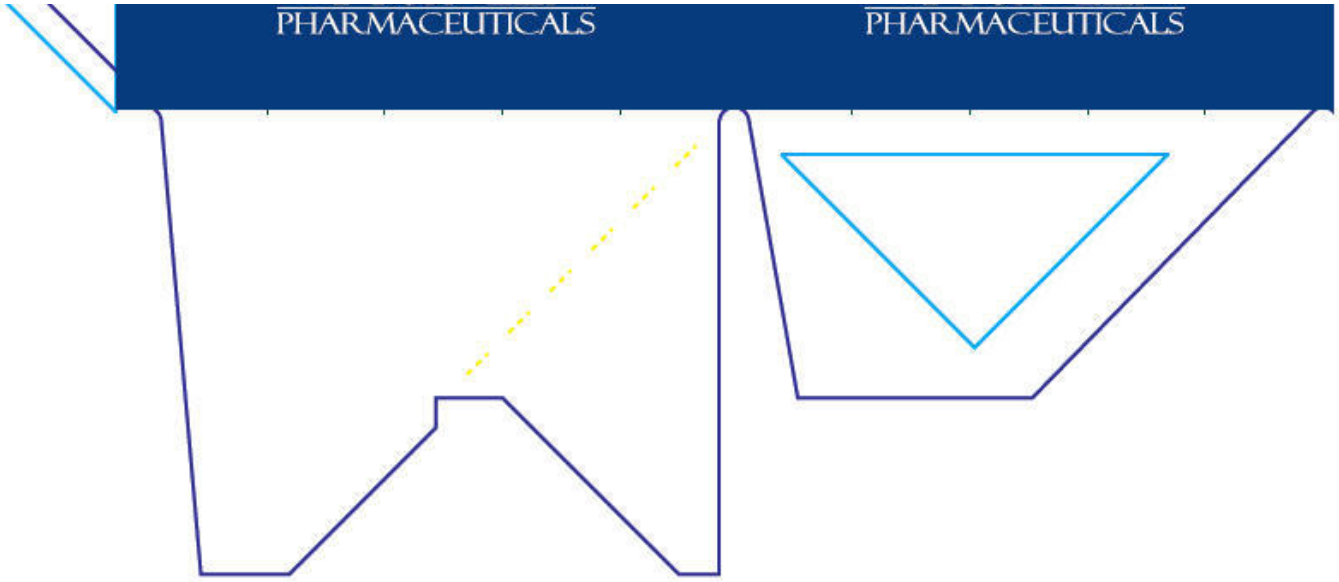
PR™ Benzoyl Peroxide Wash (7% Benzoyl Peroxide)

TOPICAL ACNE THERAPY

7%

PRUGEN™

PRUGEN™



PR BENZOYL PEROXIDE WASH

benzoyl peroxide wash lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42546-145
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	70 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
aloe (UNII: V5VD430YW9)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
cetyl alcohol (UNII: 936JST6JCN)	
DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE (UNII: 5M1101WGSY)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
laureth-12 (UNII: OAH19558U1)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
propylene glycol (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
sodium coco-sulfate (UNII: 3599J29ANH)	
sodium lauroamphoacetate (UNII: SLK428451L)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42546-145-16	1 in 1 BOX	10/26/2009	
1		473 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
unapproved drug other		10/26/2009	

Labeler - PruGen, Inc. (929922750)

Establishment

Name	Address	ID/FEI	Business Operations
PHARMASOL CORPORATION		065144289	MANUFACTURE(42546-145)

Revised: 6/2018 PruGen, Inc.