

**BENZEPRO CREAMY WASH- benzoyl peroxide soap  
PruGen, Inc.**

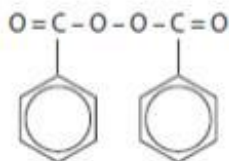
*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**BenzePrO Creamy Wash**

BenzePro™ Creamy Wash benzoyl peroxide 7.0%  
PruGen, Inc. Pharmaceuticals

**DESCRIPTION:**

BenzePro™ Creamy 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 as a keratolytic. Benzoyl Peroxide (C<sub>14</sub>H<sub>10</sub>O<sub>4</sub>) is represented by the following chemical structure:



Each gram of BenzePro™ Creamy Wash contains 70 mg of Benzoyl Peroxide as microsphere particles (via Curoxyl® 42) 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:**

BenzePro™ Creamy Wash is indicated for the topical treatment of acne vulgaris.

**CONTRAINDICATIONS:**

BenzePro™ Creamy Wash is contraindicated in persons with a known hypersensitivity to any of its ingredients.

**WARNINGS:**

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

### **PRECAUTIONS:**

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:**

General: If accidental contact occurs with eyes, mouth, or mucous membranes, rinse with water.

### **Carcinogenesis, 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.

### **Nursing Mothers:**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Benzoyl Peroxide is administered to a nursing woman.

### **Pediatric Use:**

Safety and effectiveness in children have not been established.

### **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:**

BenzePrO™ Creamy 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 off cleanser sooner or using less often.

- If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

#### **HOW SUPPLIED:**

BenzePrO™ Creamy Wash is supplied in a 180 g bottle (NDC 42546-017-18).

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.**

Manufactured for:

PruGen, Inc. Pharmaceuticals  
18899 North Thompson Peak Parkway  
Scottsdale, AZ 85255

#### **PRINCIPAL DISPLAY PANEL - 180 g Tube Label**

NDC 42546-017-18

Rx only

PRUGEN™

PHARMACEUTICALS

**BenzePrO™**

Creamy Wash

benzoyl peroxide

7.0%

Net Wt 180 g

Manufactured for:

PruGen, Inc. Pharmaceuticals  
Scottsdale, AZ 85255

[www.prugen.com](http://www.prugen.com)

Rev 1.1

NDC 42546-017-18  
Rx only



# BenzePro™

Creamy Wash  
benzoyl peroxide 7.0%

Net Wt 180 g

Manufactured for:  
PruGen, Inc. Pharmaceuticals  
Scottsdale, AZ 85255  
www.pru-gen.com  
Rev 1.0



## Drug Facts

Active ingredient (in each g)	Purpose
Benzoyl Peroxide (in microsphere particles) 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.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** See package insert for full prescribing information. Apply **BenzePro™ Creamy 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. ■ 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 controlled room temperature 20°-25° C (68°-77° F); excursions permitted to 15°-30° C (59°-86° F).
- 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 www.pru-gen.com

## BENZEPRO CREAMY WASH

benzoyl peroxide soap

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:42546-017
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	7 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE (UNII: 5M1101WGSY)

EDETATE DISODIUM (UNII: 7FLD91C86K)

GLYCERIN (UNII: PDC6A3C0OX)

GREEN TEA LEAF (UNII: W2ZU1RY8B0)

LAURETH-12 (UNII: OAH19558U1)

MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0K00R)

SODIUM COCO-SULFATE (UNII: 3599J29ANH)

SODIUM LAURO AMPHO ACETATE (UNII: SLK428451L)

XANTHAN GUM (UNII: TTV12P4NEE)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42546-017-18	180 g in 1 TUBE; Type 0: Not a Combination Product	07/01/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		07/01/2015	

**Labeler** - PruGen, Inc. (929922750)

### Establishment

Name	Address	ID/FEI	Business Operations
PHARMASOL CORPORATION		065144289	MANUFACTURE(42546-017)

Revised: 7/2018

PruGen, Inc.