

## **BENZEPRO- benzoyl peroxide cloth** **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.*

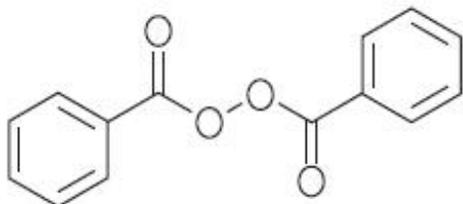
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**BenzePrO<sup>®</sup>**  
**Foaming Cloths**  
**benzoyl peroxide 6.0%**

**Rx Only**

### **DESCRIPTION**

BenzePrO<sup>®</sup> Foaming Cloths are a topical preparation containing 6.0% benzoyl peroxide. Each gram of BenzePrO<sup>®</sup> Foaming Cloths wash contains 60 mg of Benzoyl Peroxide as micronized particles. Ingredients include Purified Water, Carbomer 1342, Sodium Hyaluronate, Cetyl Alcohol, Glycerine, Hydroxypropyl Methylcellulose, Sodium Cocoyl Isethionate, Sodium Methyl Cocoyl Taurate, Sodium Lauryl Sulfoacetate and Disodium Laureth Sulfosuccinate, Sodium PCA, Sodium Hydroxide 10% Solution, Zinc Lactate, Citric Acid, Sodium Citrate, Benzoyl Peroxide 6.0%, Docusate Sodium.

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 structure:



### **CLINICAL PHARMACOLOGY**

The exact method of action of benzoyl peroxide in acne vulgaris is not known. Benzoyl peroxide is an antibacterial agent with demonstrated activity against *Propionibacterium acnes*. This action, combined with the mild keratolytic effect of benzoyl peroxide, is believed to be responsible for its usefulness in acne. Benzoyl peroxide is absorbed by the skin where it is metabolized to benzoic acid and excreted as benzoate in the urine.

### **INDICATIONS AND USAGE**

BenzePrO<sup>®</sup> Foaming Cloths are indicated for use in the topical treatment of mild to moderate acne vulgaris.

## **CONTRAINDICATIONS**

BenzePrO<sup>®</sup> Foaming Cloths should not be used in patients who have shown hypersensitivity to benzoyl peroxide or to any of the other ingredients in the product. Discontinue use if hypersensitivity is observed.

## **WARNINGS**

FOR EXTERNAL USE ONLY. Not For Ophthalmic Use. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**When using this product, skin irritation and dryness is more likely to occur if:**

- you leave BenzePrO<sup>®</sup> Foaming Cloths on your skin longer than directed
- you use another topical acne medication at the same time

**Do not use this product 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, 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 lower concentration.

**Stop use and ask a doctor:**

- if irritation becomes severe.

## **PRECAUTIONS**

### **General**

If severe irritation develops, discontinue use and institute appropriate therapy.

### **Information for patients**

This medication is to be used as directed by a physician and should not be used to treat any condition other than that for which it was prescribed. Avoid contact with eyes, eyelids, lips, and mucous membranes. If accidental contact occurs, rinse with water. If excessive redness or irritation develops, discontinue use and consult your physician.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Based upon all available evidence, benzoyl peroxide is not considered to be a carcinogen. However, data from a study using mice known to be highly susceptible to cancer suggest that benzoyl peroxide acts as a tumor promoter. The clinical significance of the findings is not known.

### **Pregnancy**

Category C animal reproduction studies have not been conducted with benzoyl peroxide. It is also 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.

### **Nursing Mothers**

It is not known whether this drug is excreted in the 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 below the age of 12 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.

### **DIRECTIONS**

**Avoid contact with hair, fabrics or carpeting as benzoyl peroxide will cause bleaching or discoloration.**

Wash affected areas once or twice daily, or as directed by your physician.

1. Wet face with water.
  2. Wet cloth with a little water and work into a full lather.
  3. Cleanse face with cloth for 10-20 seconds avoiding eyes.
  4. Rinse thoroughly and pat dry.
  5. Throw away cloth. Do not flush.
- 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<sup>®</sup> Foaming Cloths are supplied in a carton containing 60 × 3.2 g individually wrapped benzoyl peroxide 6% foaming cloths (NDC 42546-016-60).

Store at room temperature: 15° - 25°C (59° - 77°F). Protect from freezing.

Manufactured for:

**PruGen Pharmaceuticals**  
18899 N Thompson Peak Pkwy  
Scottsdale, AZ 85255  
www.pruGen.com

Rev. 3.0

**PRINCIPAL DISPLAY PANEL - 60 Cloth Packet Carton**

NDC 42546-016-60  
Rx only

**BenzePro®**

Foaming Cloths  
benzoyl peroxide 6.0%

**60**  
cloths  
Net wt. 3.2 g each

PRUGEN  
PHARMACEUTICALS

NDC 42546-016-60  
Rx only

# BenzePrO<sup>®</sup>

Foaming Cloths  
benzoyl peroxide

6.0%

60

cloths Net wt. 3.2 g each

PRUGEN  
PHARMACEUTICALS

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Area

60 cloths Net wt. 3.2 g each

60

PRUGEN  
PHARMACEUTICALS

benzoyl peroxide  
Foaming Cloths  
Benzepro®  
6.0%

NDC 42546-016-60  
Rx only



NDC 42546-016-60  
Rx only

BenzePro®

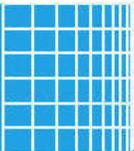
Foaming Cloths  
benzoyl peroxide

6.0%

Glue

60  
cloths Net wt. 3.2 g each

PRUGEN  
PHARMACEUTICALS



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### Drug Facts

Active ingredient (in each gram)	Purpose
Benzoyl Peroxide (as micronized particles) 60 mg .....	Acne Treatment

**Uses** Indicated for topical treatment of mild to moderate 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.  
Wash affected areas once or twice daily, or as directed by your physician.

1. Wet face with water.
2. Wet cloth with a little water and work into a full lather.
3. Cleanse face with cloth for 10-20 seconds avoiding eyes.
4. Rinse thoroughly and pat dry.
5. Throw away cloth. Do not flush.

■ 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 room temperature 15°-25° C (59°-77° F) ■ protect from freezing

**Inactive ingredients** Purified Water, Carbomer 1342, Sodium Hyaluronate, Cetyl Alcohol, Glycerine, Hydroxypropyl Methylcellulose, Sodium Cocoyl Isethionate, Sodium Methyl Cocoyl Taurate, Sodium Lauryl Sulfoacetate and Disodium Laureth Sulfosuccinate, Sodium PCA, Sodium Hydroxide 10% Solution, Zinc Lactate, Citric Acid, Sodium Citrate, Benzoyl Peroxide 6.0%, Docusate Sodium.

**Questions?** 866-696-8525 [www.prugen.com](http://www.prugen.com)

Manufactured for:  
PruGen Pharmaceuticals  
Scottsdale, AZ 85255  
[www.prugen.com](http://www.prugen.com)  
Rev 3.0



N 3 42546 01660 3

Glue

NDC 42546-016-60  
Rx only

**BenzePrO<sup>®</sup>**

Foaming Cloths  
benzoyl peroxide

6.0%

60

cloths Net wt. 22 grams

PRUGEN



Glue

## BENZEPRO

benzoyl peroxide cloth

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:42546-016
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Benzoyl Peroxide</b> (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	60 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0KO0R)	
<b>Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked)</b> (UNII: 809Y72KV36)	
<b>Hyaluronate Sodium</b> (UNII: YSE9PPT4TH)	
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
<b>Glycerin</b> (UNII: PDC6A3C00X)	
<b>HYPROMELLOSE 2910 (15 MPA.S)</b> (UNII: 36SFW2JZ0W)	
<b>Sodium Cocoyl Isethionate</b> (UNII: 518XTE8493)	
<b>Sodium Methyl Cocoyl Taurate</b> (UNII: JVL98CG53G)	
<b>Sodium Lauryl Sulfoacetate</b> (UNII: D0Y70F2B9J)	
<b>Disodium Laureth Sulfosuccinate</b> (UNII: D6DH1DTN7E)	
<b>Sodium Pyrrolidone Carboxylate</b> (UNII: 469OTG57A2)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Zinc Lactate</b> (UNII: 2GXR25858Y)	
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	

**Sodium Citrate, Unspecified Form** (UNII: 1Q73Q2JULR)

**Docusate Sodium** (UNII: F05Q2T2JA0)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42546-016-60	60 in 1 CARTON	08/01/2015	
1		1 in 1 PACKET; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		08/01/2015	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Span Packing Services		557434805	MANUFACTURE(42546-016)

Revised: 1/2022

PruGen, Inc.