

**BENZEPRO- benzoyl peroxide aerosol, foam**  
**PruGen, Inc.**

*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.*

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**BenzePro Short Contact Foam**

**BenzePrO™ Short Contact Foam**

***Drug Facts***

***Active ingredients***

Benzoyl Peroxide 9.8%

***Purpose***

Acne Treatment

***Uses***

Indicated for the 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 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, possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration

**Stop 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***

**Prime can before initial use:** See package insert **Before Each Use:** Shake vigorously

**During Use:** Holding can upright, dispense into palm of hand and apply to affected area as directed by physician.

- 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
- Store upright

***Inactive ingredients***

BHT, C12-15 alkyl benzoate, cetostearyl alcohol, citric acid, dimethicone, disodium EDTA, emulsifying wax, glycerin, methylparaben, povidone, propylene glycol, propylparaben, purified water, sodium citrate, steareth-10, stearic acid, trolamine. Also contains: Propellant HFA-134A (1, 1, 1, 2-tetrafluoroethane).

Questions? 866-696-8525

Manufactured for:

PruGen, Inc.

Pharmaceuticals

18899 North Thompson Peak Parkway

Scottsdale, AZ 85255

REV 1.2

**PRINCIPAL DISPLAY PANEL - 100 g Canister Box**

**NDC 42546-015-10**

**Rx only**

**BenzePrO®**

Short Contact Foam

benzoyl peroxide

**9.8%**

**For topical treatment  
of mild to moderate  
acne vulgaris**

**Net Weight 100 g**

Will not dispense entire contents.

Container is overfilled to guarantee  
dispensing at least the listed amount.

PRUGEN™

PHARMACEUTICALS

BenzePrO®  
Short Contact Foam  
benzoyl peroxide 9.8%

**Drug Facts**

**Active ingredient (in each gram)**  
Benzoyl Peroxide 98 mg

**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.**  
**Prime can before initial use:** Shake can vigorously. Hold can upright over sink. Direct initial spray to a non-skin surface. Press down on actuator.  
**Before Each Use:** Shake vigorously.  
**During Use:** Holding can upright, dispense BenzePrO® Emollient Foam into palm of hand and apply to affected area once daily, or as directed by a physician. Wipe off any excess foam from actuator after use. Wash hands with soap and water after applying BenzePrO® Emollient Foam.  
■ If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

**Drug Facts (continued)**

**Other information**

- store at room temperature 15°-25° C (59°-77° F)
- protect from freezing
- store upright

**Inactive ingredients** BHT, C12-15 alkyl benzoate, cetostearyl alcohol, citric acid, dimethicone, disodium EDTA, emulsifying wax, glycerin, methylparaben, povidone, propylene glycol, propylparaben, purified water, sodium citrate, steareth-10, stearic acid, trolamine. Also contains: Propellant A31 (isobutane).

**Questions?** 866-696-8525

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**For topical treatment of mild to moderate acne vulgaris**

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**PRUGEN®**  
PHARMACEUTICALS

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

Rev 2.0

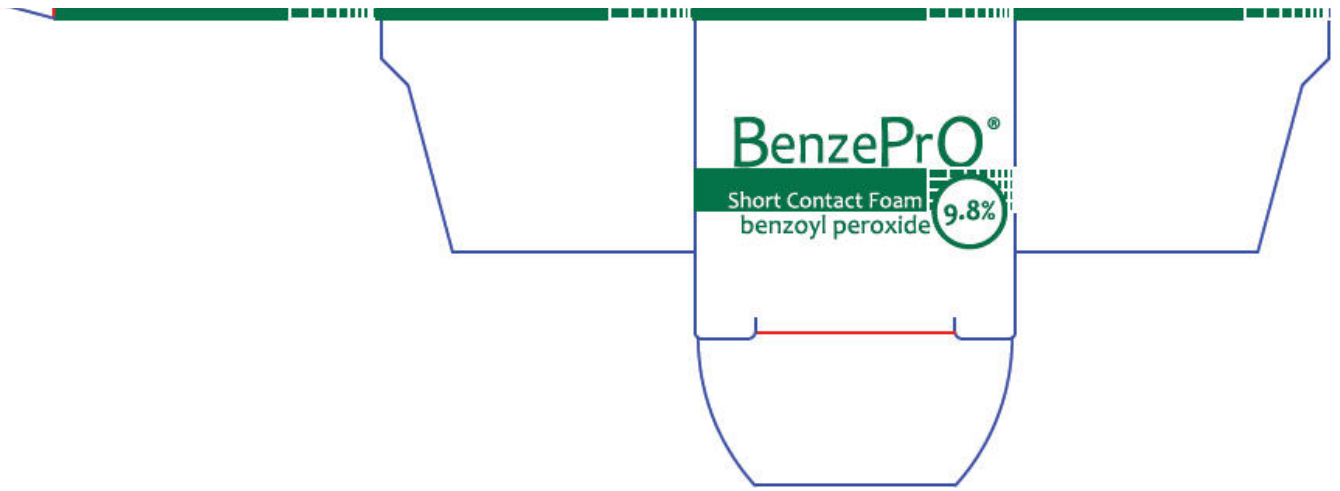
3 42546 01510 1

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## BENZEPRO

benzoyl peroxide aerosol, foam

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42546-015
<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	9.8 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
STEARETH-10 (UNII: FD0913P475)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42546-015-10	1 in 1 BOX	07/01/2012	
1		100 g in 1 CANISTER; Type 0: Not a Combination Product		
2	NDC:42546-015-01	8 in 1 CARTON	07/01/2012	
2		5 g in 1 CANISTER; 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	07/01/2012	

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

### Establishment

Name	Address	ID/FEI	Business Operations
PHARMASOL CORPORATION		065144289	MANUFACTURE(42546-015)

Revised: 6/2018

PruGen, Inc.