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.

BenzePro Emollient Foam

BenzePrO™ Emollient Foam

Drug Facts

Active ingredients

Benzoyl Peroxide 5.3%

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, Arizona 85255 REV 1.2

PRINCIPAL DISPLAY PANEL - 100 g Can Box

NDC 42546-010-10
Rx only

BenzePrO®

Emollient Foam
benzoyl peroxide
5.3%

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

Drug Facts

Active ingredient (in each gram)
Benzoyl Peroxide 53 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*

PRUGEN PHARMACEUTICALS

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

Rev 2.0

N 3 42546 01010 6

NDC 42546-010-10
Rx only

BenzePrO®
Emollient Foam 5.3%
benzoyl peroxide

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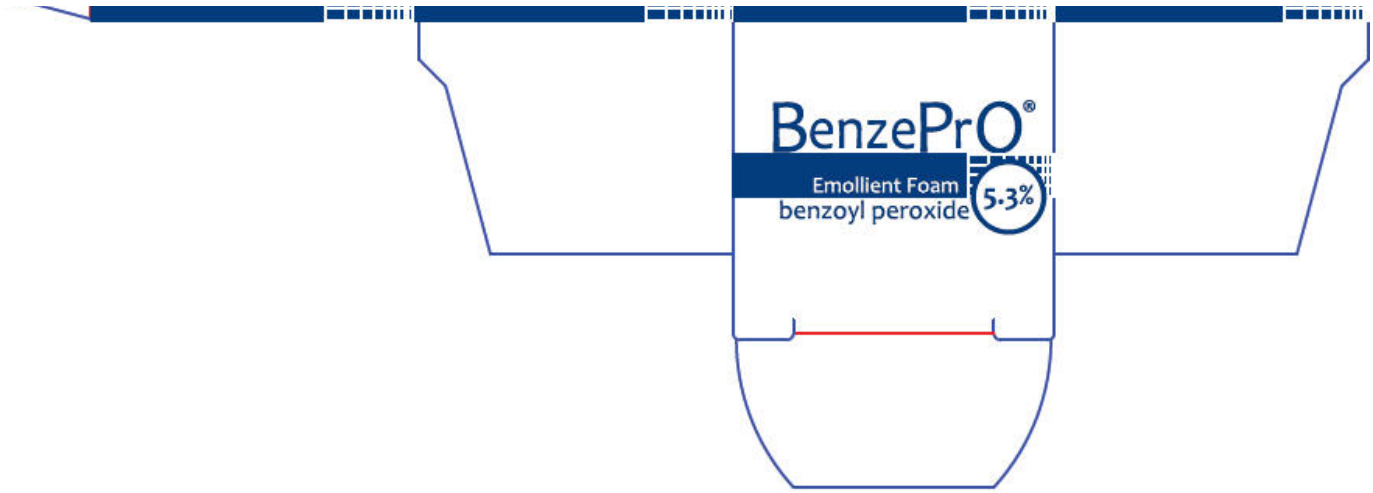

BENZEPRO

benzoyl peroxide aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42546-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	3.18 g in 60 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
STEARETH-10 (UNII: FD0913P475)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42546-010-10	1 in 1 BOX	07/01/2012	
1		100 g in 1 CAN; Type 0: Not a Combination Product		
2	NDC:42546-010-01	8 in 1 CARTON	07/01/2012	
2		5 g in 1 CANISTER; Type 0: Not a Combination Product		
3	NDC:42546-010-06	1 in 1 BOX	07/01/2012	
3		60 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(42546-010)

Revised: 6/2018 PruGen, Inc.