

BENZOYL PEROXIDE CLEANSER- benzoyl peroxide gel
Pharmco Laboratories Inc.

Benzoyl Peroxide Cleanser 3.5%

Drug Facts

Active Ingredient

Benzoyl Peroxide 3.5%

Purpose

Acne Treatment

Uses

- For the treatment of acne.

Warnings

- For external use only

Do not use if you

- Have very sensitive skin
- Are sensitive to benzoyl peroxide

When using this product

- Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- 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.
- If going outside, apply sunscreen after using this product.
- If sensitivity develops or irritation becomes severe, stop use and ask a doctor.
- Keep out of reach of children
- If swallowed get medical help or call a poison control center immediately
- Keep away from excessive heat or heat sources

Directions

- Use once or twice daily. Morning and/or night.
- Apply to damp skin and Wash-In for up to 1 minute.
- Do not get in the eyes.
- For best results, use fingertips and apply to affected areas with gentle pressure in a circular motion.
- Rinse off with warm water and pat dry with soft towel.
- If going outside, apply broad spectrum sunscreen SPF 15 or higher.

Other Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, C12-14 Alkyl Olefin Sulfonate, Disodium Cocoamphodiacetate, Edetate Disodium, Ethylhexylglycerin, FD&C Yellow # 5, Glycerine, Panthenol, Perlite, Phenoxyethanol, Propylene Glycol, Sodium Hyaluronate, Sodium Hydroxide, Water

Other Information

Store at 15 - 25°C (59 - 77°F) Protect from heat. Keep container tightly closed.

Manufactured by:

Pharmco Laboratories Inc. • Titusville, FL 32780

PRINCIPAL DISPLAY PANEL - 170 g Bottle Label

PHARMCO

SKINCARE LABS

Benzoyl Peroxide
Cleansing Gel 3.5%

Net wt. 6 oz. (170 g)

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Manufactured by: Pharmco Laboratories Inc. • Titusville, FL 32780 www.pharmcolabs.com • 1.800.635.0712 Reorder CPL07-6	

PLOT-REV0001

BENZOYL PEROXIDE CLEANSER

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58400-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	35 mg in 1 g
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Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
SODIUM C12-14 OLEFIN SULFONATE (UNII: 7I962MCQ71)	
Disodium Cocoamphodiacetate (UNII: 18L9G3U51M)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
PERLITE (UNII: 0SG101ZGK9)	
Allantoin (UNII: 344S277G0Z)	
Panthenol (UNII: WW9CM0067Z)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
Edetate Disodium (UNII: 7FLD91C86K)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Sodium Hydroxide (UNII: 55X04QC32I)	
FD&C Yellow NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58400-009-01	170 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/01/2016	
2	NDC:58400-009-02	3900 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M006	12/01/2016	

Labeler - Pharmco Laboratories Inc. (096270814)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmco Laboratories Inc.		096270814	MANUFACTURE(58400-009) , LABEL(58400-009) , PACK(58400-009) , ANALYSIS(58400-009)