MICRONIZED BPO SCRUB- benzoyl peroxide gel
Pharmco Laboratories 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.

Micronized BPO Scrub 5%

Drug Facts

Active Ingredient

Benzoyl Peroxide 5%

Purpose

Acne Treatment

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

Apply a quarter-sized amount to damp skin with gentle pressure and work into lather. Rinse with lukewarm water and pat dry with soft towel. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two to three times daily or as directed by a physician or skincare professional. If bothersome dryness or peeling occurs, reduce frequency of applications. If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use and consult a physician or skin care professional.

Other Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, C12-14 Alkyl Olefin Sulfonate, Disodium Cocoamphodiacetate, Edetate Disodium, Ethylhexylglycerin, Glycerin, Panthenol, Phenoxyethanol, Polyethylene, Propylene Glycol, Sodium Hyaluronate, Sodium Hydroxide.

Other Information

Store at 20 - 25°C (68 - 77°F) Protect from heat. Keep container tightly closed.

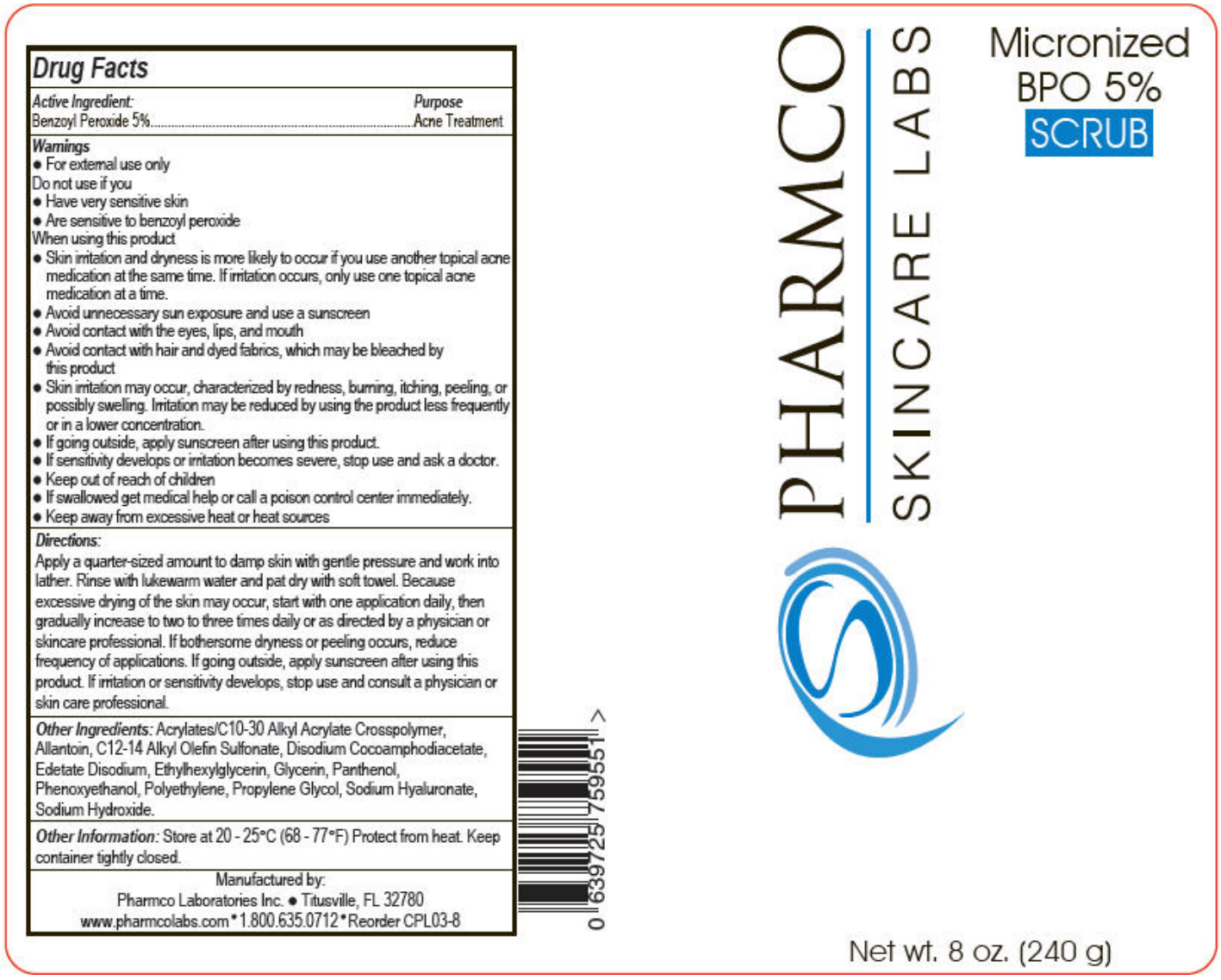
Manufactured by:
Pharmco Laboratories Inc. • Titusville, FL 32780
www.pharmcolabs.com • 1.800.635.0712 • Reorder CPL03-8

PRINCIPAL DISPLAY PANEL - 240 g Bottle Label

PHARMCO
SKINCARE LABS

Micronized
BPO 5%
SCRUB

Net wt. 8 oz. (240 g)



MICRONIZED BPO SCRUB

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58400-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	50 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Disodium Cocoamphodiacetate (UNII: 18L9G3U51M)	

Allantoin (UNII: 344S277G0Z)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Panthenol (UNII: WV9CM0O67Z)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Edetate Disodium (UNII: 7FLD91C86K)	
Sodium Hydroxide (UNII: 55X04QC32I)	
High Density Polyethylene (UNII: UG00KM4WR7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58400-005-01	240 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		
2	NDC:58400-005-02	3900 g in 1 BOTTLE, PLASTIC; 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	06/01/2012	

Labeler - Pharmco Laboratories Inc. (096270814)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmco Laboratories Inc.		096270814	MANUFACTURE(58400-005) , LABEL(58400-005) , PACK(58400-005) , ANALYSIS(58400-005)

Revised: 2/2015 Pharmco Laboratories Inc.