MICRONIZED BENZOYL PEROXIDE TREATMENT- 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 Benzoyl Peroxide Treatment 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

- Clean the skin thoroughly before applying this product
- Cover the entire affected area with a thin layer one to three times daily
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- Other sun protection measures include limiting sun exposure and wearing protective clothing.

Other Ingredients

Carbomer, Edetate Disodium, Glycerine, Propylene Glycol, Saccharide Isomerate, Sodium Hydroxide, Water.

Other Information

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

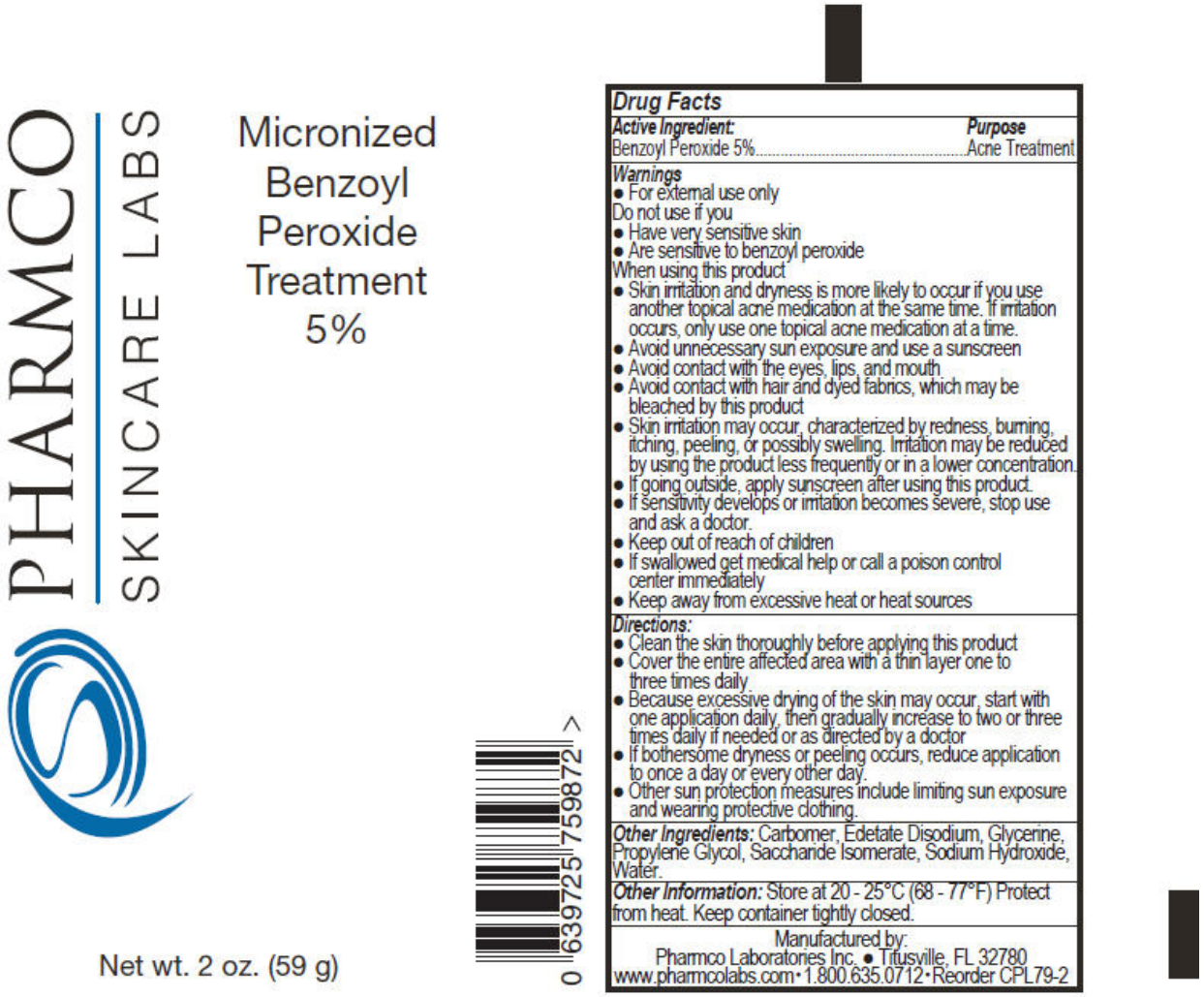
Manufactured by:
Pharmco Laboratories Inc. • Titusville, FL 32780
www.pharmcolabs.com • 1.800.635.0712 • Reorder CPL79-2

PRINCIPAL DISPLAY PANEL - 59 g Tube Label

PHARMCO
SKINCARE LABS

Micronized
Benzoyl
Peroxide
Treatment
5%

Net wt. 2 oz. (59 g)



MICRONIZED BENZOYL PEROXIDE TREATMENT

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58400-002
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)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Edetate Disodium (UNII: 7FLD91C86K)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Saccharide Isomerate (UNII: W8K377W98I)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58400-002-01	59 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:58400-002-02	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(58400-002) , LABEL(58400-002) , PACK(58400-002) , ANALYSIS(58400-002)