MICRONIZED BENZOYL PEROXIDE TREATMENT- benzoyl peroxide gel Pharmco Laboratories Inc.

Micronized Benzoyl Peroxide Treatment 10%

Drug Facts

Active Ingredient

Benzoyl Peroxide 10%

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

- 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.
- If going outside, apply broad spectrum sunscreen SPF 15 or higher.

Other Ingredients

Carbomer, Edetate Disodium, Glycerine, Propylene Glycol, Saccharide Isomerate, 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 www.pharmcolabs.com • 1.800.635.0712 • Reorder CPL78-2

PRINCIPAL DISPLAY PANEL - 59 g Tube Label

PHARMCO

SKINCARE LABS

Micronized Benzoyl Peroxide Treatment Gel 10%

Net wt. 2 oz. (59 g)



Net wt. 2 oz. (59 g)

Treatment Gel 10%

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 Keep away from excessive hea 	t or heat sources
Directions: Clean the skin thoroughly before the entire affected area three times daily. He grade three times daily, then gradings daily freeded or as drest the standard of the day or every other design, and or grade the standard or property. The standard of the day or every other design of the day or every other design.	re applying this product with a thin layer one to e skin may occur, start with ually increase to two or three teed by a doctor ig occurs, reduce application by. ectrum sunscreen
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Manufacto Pharmoo Laboratories Inc.	Titusville, Florida 32780

PLOTC-REV0001

MICRONIZED BENZOYL PEROXIDE TREATMENT

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58400-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Benzoyl Peroxide (UNII: W9WZ N9A0GM) (Benzoyl Peroxide - UNII: W9WZ N9A0GM)	Benzoyl Peroxide	100 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		
NDC:58400- 003-01	59 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2012			
NDC:58400- 003-02	3900 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2012			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	06/01/2012	

Labeler - Pharmco Laboratories Inc. (096270814)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharmco Laboratories Inc.		096270814	MANUFACTURE(58400-003) , LABEL(58400-003) , PACK(58400-003) , ANALYSIS (58400-003)

Revised: 1/2024 Pharmco Laboratories Inc.