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)

Drug Facts

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Uses
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Warnings
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- Are sensitive to benzoyl peroxide

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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: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	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
1	NDC:58400-003-01	59 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2012	
2	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.