PROSKI BENZO- benzoyl peroxide gel PHARMAMED USA INC

BENZOYL PEROXIDE GEL BP

ACTIVE INGREDIENT

Benzoyl peroxide 5%

PURPOSE

Acne treatment

USE

For the treatment of acne

WARNING

To be sold by retail on the prescription of a Registered Medical Practitioner only

DO NOT ACCEPT IF TAGGER IS BROKEN. USE THE BUILT-IN PIN ON THE CAP TO PIERCE THE TAGGER

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.

Stop use and ask a doctor if

irritation becomes severe

Keep out of reach of children

Avoid contact with eyes and mouth.

Keep the tube tightly closed after use.

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

DIRECTIONS

Sensitivity Test for a New User. Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below. 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 sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

OTHER INFORMATION

Storage: store in a cool dry place at 20°-25°C (68°-77°F). Do not freeze

INACTIVE INGREDIENTS

methylparaben, polysorbate 80, sodium hydroxide, purified water, carbomer homopolymer

QUESTIONS OR COMMENTS?

(754) 200-8994 (Mon-Fri 8 AM to 4 PM EST)

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 84289-216-20

Benzoyl Peroxide Gel BP

Net Wt. 20g

GOA/DRUGS/571





PROSKI BENZO benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84289-216
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII: W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
METHYLPARABEN (UNII: A218C7HI9T)		
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)		
ROSE OIL (UNII: WUB68Y35M7)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
WATER (UNII: 059QF0KO0R)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:84289-216- 20	1 in 1 CARTON	04/01/2025			
1		20 g in 1 TUBE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M006	04/01/2025		

Labeler - PHARMAMED USA INC (065607328)

Revised: 3/2025 PHARMAMED USA INC