BENZOYL PEROXIDE- benzoyl peroxide gel Innovida Pharmaeutique Corporation

Active Ingredient

Benzoyl peroxide 5%

Purpose

Acne treatment

Uses

For the treatment of acne

Warnings

For external use only

Do not use this medication if you have very sensitive skin or if you are sensitive to benzoyl peroxide.

When using this product keep away from eyes, lips and mouth

• avoid unnecessary sun exposure and use a sunscreen

• avoid contact with hair or dyed fabric, including carpet and clothing which may be bleached by this product

• skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Mild irritation may be reduced by using the product less frequently or in a lower concentration. If irritation becomes severe, discontinue use; if irritation still continues, consult a doctor.

• using other topical acne medication at the same time or immediately following the use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with the eyes. If contact occurs, flush thoroughly with water.

Directions

Cleanse skin thoroughly before applying medication. Cover the entire affected area with a thin layer 1-3 times daily. If bothersome dryness or peeling occurs, reduce application to once a day.

Other information

Keep tightly closed. Avoid storing at extreme temperatures (below 40° F and above 100° F).

Inactive Ingredients

carbomer, disodium EDTA, laureth-4, sodium hydroxide, titanium dioxide, water

Product label



NDC: 71800- 043 -04				
	Drug Facts Active ingredient Purpose Benzoyl peroxide 5% Acne treatment Uses For the treatment of acne			
_	Warnings . For external use only . Do not use this medication if you have very sensitive skin or if you are sensitive to benzoyl peroxide.			
Benzoyl Peroxide	When using this product • keep away from eyes, lips and moutha • void unnecessary sun exposure and use a sunscreen • avoid contact with hair or dyed fabric, including carpet and clothing which may be bleached by this product • skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Mild irritation may be reduced by using the product less frequently or in a lower concentration. If irritation becomes severe, discontinue use; if irritation still continues, consult a doctor. • using other topical acne medication at the same time or immediately following the use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.			
Acne Medication, Gel,	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with the eyes. If contact occurs, flush thoroughly with water.			
Benzoyl Peroxide 5%	Directions Cleanse skin thoroughly before applying medication. Cover the entire affected area with a thin layer 1-3 times daily. If bothersome dryness or peeling occurs, reduce application to once a day.			
TOPICAL ADMINISTRATION	Other information Keep tightly closed. Avoid storing at extreme temperatures (below 40° F and above 100° F).			
1.5 oz (42.5 g)	Inactive ingredients: carbomer, disodium EDTA, laureth-4, sodium hydroxide, titanium dioxide, water			
Mfd. for: Innovide	a Pharmaceutique Corporation, Phoenix, AZ 85040, Tel.: 888-462-4166			

BENZOYL PEROXIDE					
benzoyl peroxide gel					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:7			800-043
Route of Administration	TOPICAL				
• ·· • • · · · · •					
Active Ingredient/Active	Molety				
Ingredient Name Basis of Strength					Strength
BENZOYL PEROXIDE (UNII: W9WZ UNII:W9WZ N9A0GM)	(IDE -	BENZOYL PEROXIDE		50 mg in 1 mL	
Inactive Ingredients					
	Ingredient Name				Strength
CARBOXYMETHYLCELLULOSE S	ODIUM, UNSPECIFIED (UN	NII: K679OBS311)			
EDETATE DISODIUM (UNII: 7FLD9	1C86K)				
LAURETH-4 (UNII: 6HQ855798J)					
SODIUM HYDROXIDE (UNII: 55X04	IQC32I)				
TITANIUM DIOXIDE (UNII: 15FIX9V	(2JP)				
WATER (UNII: 059QF0K00R)					

Packaging								
# Item Code	Package Description	Marketing Start Date	Marketing End Date					
1 NDC:71800-043- 04	1 in 1 CARTON	02/10/2025						
	44 mL 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 Dru	g M006	02/10/2025						

Labeler - Innovida Pharmaeutique Corporation (080892908)

Revised: 2/2025

Innovida Pharmaeutique Corporation