RUGBY BENZOYL PEROXIDE ACNE MEDICATION- benzoyl peroxide gel Rugby Laboratories, Inc.

Rugby[®] 5% Benzoyl Peroxide Gel Acne Medication

Drug Facts

Active ingredient

Benzoyl peroxide 5%

Purpose

Acne treatment

Use

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

n 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

Questions or comments?

1-800-645-2158

Distributed by: Rugby Laboratories 31778 Enterprise Drive Livonia, MI 48150

PRINCIPAL DISPLAY PANEL - 42.5 g Tube Carton

NDC 0536-1055-56

Rugby®

Acne Medication Benzoyl Peroxide Gel USP, 5%

5

Net Wt 1.5 oz (42.5 g)



RUGBY BENZOYL PEROXIDE ACNE MEDICATION

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1055
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII: W9WZ N9A0GM)	Benzoyl Peroxide	50 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
Carboxymethylcellulose Sodium, Unspecified (UNII: K6790BS311)		
Edetate Disodium (UNII: 7FLD91C86K)		
Laureth-4 (UNII: 6HQ855798J)		
Sodium Hydroxide (UNII: 55X04QC32I)		
Titanium Dioxide (UNII: 15FIX9V2JP)		
Water (UNII: 059QF0KO0R)		

Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1055- 56	1 in 1 CARTON	01/20/2015	
1		42.5 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0536-1055- 25	1 in 1 CARTON	10/31/2019	
2		60 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0536-1055- 57	1 in 1 CARTON	10/31/2019	
3		90 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 drug	M006	01/20/2015	

Labeler - Rugby Laboratories, Inc. (079246066)

Registrant - Garcoa, Inc. (103039178)

Establishment					
Name	Address	ID/FEI	Business Operations		
Garcoa, Inc.		036464697	MANUFACTURE(0536-1055)		

Revised: 2/2024 Rugby Laboratories, Inc.