

RUGBY BENZOYL PEROXIDE WASH ACNE MEDICATION- benzoyl peroxide lotion
Rugby Laboratories

Rugby® 10% Benzoyl Peroxide Wash USP
Acne Medication

Drug Facts

Active ingredient

Benzoyl peroxide USP 10%

Purpose

Acne medication

Use

for the treatment of acne

Warnings

For external use only.

Do not use if you

- have very sensitive
- are sensitive to benzoyl peroxide

When using this product

- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with eyes, lips and mouth
- avoid contact with hair or 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.
- 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.

Stop use and consult a doctor if

- irritation becomes severe

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

- shake well
- Wet area to be cleansed
- **Sensitive 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 directions stated below
- one to three times daily, wet skin and cover the entire affected area with a thin layer, liberally applying to areas to be cleansed. Massage gently into skin for 10-20 seconds working into a full lather, rinse thoroughly and pat dry
- 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

- keep tightly closed
- store at room temperature

Inactive ingredients

carbomer, cetyl alcohol, disodium EDTA, disodium laureth sulfosuccinate, glycerin, glyceryl stearate, laureth-7, magnesium aluminum silicate, PEG-100 stearate, propylene glycol, sodium coco-sulfate, sodium lauroamphoacetate, water, xanthan gum

Questions or comments?

1-800-645-2158

Distributed by: **RUGBY® LABORATORIES**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

PRINCIPAL DISPLAY PANEL - 148 mL Bottle Label

Rugby®

NDC 0536-1261-63

Benzoyl Peroxide

Wash USP

10%

- Helps to keep skin clear
- Helps dry oily skin
- Helps clear acne pimples

5 FL OZ (148 mL)



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• **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 directions stated below • one to three times daily, wet skin and cover the entire affected area with a thin layer, liberally applying to areas to be cleansed. Massage gently into skin for 10-20 seconds working into a full lather, rinse thoroughly and pat dry • 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.

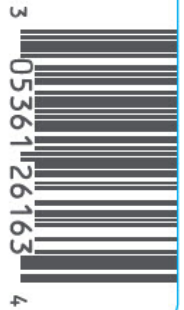
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17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
www.rugbylaboratories.com
Rev. 12/19 R-104 Re-order No. 370814
MADE IN CANADA

05-3832



RUGBY BENZOYL PEROXIDE WASH ACNE MEDICATION

benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1261
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 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Edetate Disodium (UNII: 7FLD91C86K)	
Disodium Laureth Sulfosuccinate (UNII: D6DH1DTN7E)	
Glycerin (UNII: PDC6A3C00X)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Laureth-7 (UNII: Z95S6G8201)	
Magnesium Aluminum Silicate (UNII: 6M3P64V0NC)	
PEG-100 Stearate (UNII: YD01N1999R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Coco-Sulfate (UNII: 3599J29ANH)	
Sodium Lauroamphoacetate (UNII: SLK428451L)	
Water (UNII: 059QF0KO0R)	
Xanthan Gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1261-63	148 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/17/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M006	12/17/2019	

Labeler - Rugby Laboratories (079246066)

Registrant - Garcoa, Inc. (036464697)

Establishment

Name	Address	ID/FEI	Business Operations
Sigan Industries, Inc.		255106239	MANUFACTURE(0536-1261)