

RUGBY BENZOYL PEROXIDE ACNE MEDICATION- benzoyl peroxide gel A-S Medication Solutions

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Rugby® 10% Benzoyl Peroxide Gel

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

- 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

- keep tightly closed
- store at room temperature

Inactive ingredients

carbomer, disodium EDTA, hydroxypropyl methylcellulose, laureth-4, sodium hydroxide, water

Questions or comments?

1-800-645-2158

Distributed by:

RUGBY® LABORATORIES

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

HOW SUPPLIED

Product: 50090-1792

NDC: 50090-1792-0 42.5 mL in a TUBE / 1 in a CARTON

Benzoyl Peroxide

NDC 50090-1792-0
A-S Medication Solutions, LLC
Product No. 3405-0
LOT
RUGBY ACNE MEDICATION
BENZOYL PEROXIDE GEL
10%

ACTIVE INGREDIENT
BENZOYL PEROXIDE 10%

AVOID STORING AT EXTREME
TEMPERATURES (BELOW 40
DEGREES F AND ABOVE 100
DEGREES F)
1.5 OZ (42.5G)

GTIN: 00350090179201
LOT:
S/N:

DISTRIBUTED BY:
A-S Medication Solutions
Libertyville, IL 60048
MFG: RUGBY LABORATORIES
LIVONIA, MI 48150
SOURCE NDC: 0536-1056-56



RUGBY BENZOYL PEROXIDE ACNE MEDICATION

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-1792(NDC:0536-1056)
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 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
Edetate Disodium (UNII: 7FLD91C86K)	
Laureth-4 (UNII: 6HQ855798J)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Water (UNII: 059QF0K00R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-1792-0	1 in 1 CARTON	04/28/2015	
1		42.5 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 FINAL	part333D	01/20/2015	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-1792)

Revised: 2/2023

A-S Medication Solutions