ACNE MEDICATION 5- benzoyl peroxide lotion
Rugby Laboratories

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.

BENZOYL PEROXIDE TOPICAL WASH 5% DRUG FACTS

Active ingredient

Active Ingredient

5% benzoyl peroxide

Uses

Uses

- **treats acne**
- **dries up acne pimples**
- **helps prevent new acne pimples**

Warnings

Warnings

For external use only

Do not use if you

Do not use

if you have very sensitive skin or if you are sensitive to benzoyl peroxide.

Stop use and ask a doctor

Stop use and ask a doctor if irritation becomes severe and continues.

Keep out of reach of children

Keep out of reach of children.

If swallowed, get medical help or contact Poison Control Center right away.

Directions

Directions

- shake well before use
- clean the skin thoroughly before applying this product
- cover 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 use sunscreen after using this product. If irritation or sensitivity develops, discontinue use of both products and consult a doctor

- 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 above

Other information

Other Information

to prevent bleaching, avoid contact with hair or dyed fabric and clothing

KEEP TIGHTLY CLOSE

store at room temperature 15°-30°C (59°-86°F)

Lot number and expiration date: See box or bottle

When using this product

When using this product

- **avoid unnecessary sun exposure and use a sunscreen**
- using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one drug should be used unless directed by a doctor.
- irritation may develop, such as redness, burning, itching,peeling, or possibly swelling
- more frequent use or higher concentrations may aggravate such irritation
- mild irritation may be reduced by using the product less frequently or in lower concentration
- **keep away from eyes, lips, mouth**
- IT MAY BLEACH HAIR OR DYED FABRICS

Inactive ingredients

Inactive Ingredients

Brij 30, carbomer, diisopropanolamine, disodium edetate, purified water

Distributed by:

RUGBY LABORATORIES
LIVONIA, MI 48150 USA

Principal Display Panel

PRINCIPAL DISPLAY PANEL 8OZ BOTTLE LABEL

NDC 0536-0810-95
BENZOYL PEROXIDE 5%
Clear Up Acne Pimples

FOR TOPICAL USE

Net Weight 1 fl oz

SAVE BOX FOR COMPLETE DRUG FACTS

Drug Facts

Active ingredient	**Purpose**
Benzoyl peroxide 5%	Acne treatment

Uses • treats acne • dries up acne pimples • helps prevent new acne pimples

Warnings

For external use only

Do not use if you • have very sensitive skin • are sensitive to benzoyl peroxide

When using this product • 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.
- skin irritation and dryness are 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 ask a doctor if irritation becomes severe

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- SHAKE WELL BEFORE USE
- clean the skin thoroughly before applying this product
- cover 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.
- *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 above.

Other information • store at room temperature 15° - 30°C (59° - 86°F)
- Lot No. & Exp. Date: see box or bottle

Inactive ingredients Brij 30, carbomer, diisopropanolamine, disodium edetate, purified water

Questions or comments? call 1-800-645-2158, 9 am - 5 pm ET, Monday - Friday

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Mfd for:
Rugby Laboratories, Inc.
Duluth, Georgia 30097
www.rugbylaboratories.com

R0111

Rugby®

NDC 0536-0810-95

Acne Medication

Benzoyl Peroxide Lotion, 5%

1 fl oz (30 mL)

Rugby — Satisfaction Guaranteed or Your Money Back

- Helps dry oily skin
- Helps clear acne pimples

Rugby®

HELPS TO

CLEAR UP ACNE PIMPLES

AND KEEP SKIN CLEARER
- Odorless
- Colorless
- Greaseless
- Vanishing Formula

Purpose

Acne treatment

Questions?

Call 1-(800) 645-2158

ACNE MEDICATION 5

benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-0810
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	50 mg in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STEARETH-30 (UNII: 5776GCL1DG)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
DIISOPROPANOLAMINE (UNII: 0W44HYL8T5)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-0810-95	30 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	10/29/2012	

Labeler - Rugby Laboratories (191427277)

Revised: 1/2013

Rugby Laboratories