

## **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.*

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## **BENZOYL PEROXIDE TOPICAL WASH 5% DRUG FACTS**

### **Active ingredient**

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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**

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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**

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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**



## 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		

### 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

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