

ACNE MEDICATION 10- 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 10% DRUG FACTS

Active ingredient

Active Ingredient

10% benzoyl peroxide

Uses

Uses

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

Warnings

Warnings

For external use only

Do not use

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
- 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 gradual increase to two three times daily 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 New Users: 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 No. & Exp. Date: See box or bottle

Purpose

Purpose

Acne Treatment

When using this product

When using this product

- **avoid unnecessary sun exposure and use a sunscreen**
- **avoid contact with the eyes, lips and mouth**
- 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.
- skin irritation may develop, such as redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration
- 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
- **IT MAY BLEACH HAIR OR DYED FABRICS**

Inactive ingredients

Inactive Ingredients

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

Distributed by:

Rugby Laboratories

Livonia, MI 48150 USA

Principal display panel

NDC 0536-0815-95

BENZOYL PEROXIDE 10%

FOR TOPICAL USE

Rugby

HELPS TO CLEAR UP ACNE PIMPLES

AND KEEP SKIN CLEARER

- Odorless
- Colorless
- Greaseless
- Vanishing Formula

- Helps dry oily skin
- Helps clear acne pimples



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Acne Medication

Benzoyl Peroxide Lotion, 10%
1 fl oz (30 mL)

NDC 0536-0815-95

Rugby



SAVE BOX FOR COMPLETE DRUG FACTS

Drug Facts	
Active ingredient	Purpose
Benzoyl peroxide 10%	Acne treatment
Uses • treats acne • dries up acne pimples • helps prevent new acne pimples	
Warnings	
<i>For external use only</i>	
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 Bq 30, carbonic, disopropylamine, disodium edetate, purified water	
Questions or comments? call 1-888-645-2158, 9 am - 5 pm ET, Monday - Friday	

Rugby

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



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Questions?

Call 1-(800) 645-2158

ACNE MEDICATION 10

benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-0815
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 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	
STEARETH-30 (UNII: 5776GCL1DG)	
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:0536-0815-95	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)