ACNE MEDICATION 5- benzoyl peroxide gel 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.

Drug Facts

Active Ingredient

Benzoyl peroxide 5%

Purpose

Acne Treatment

Keep out of reach of children

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

Directions

- 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.

Warning

For external use only

Dosage

Use twice daily or as directed by Physician.

Inactive Ingredients

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

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

Uses

- treats acne
- dries up acne pimples

• helps prevent new acne pimples

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 possible swetting. 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

Other information

Store at room temperature 15 degrees to 30 degrees C (59 degrees to 86 degrees F) For lot number and expiration date: See box or crimp of tube

Questions or comments?

Call 1-800-645-2158

Principal display panel



ACNE MEDICATION 5

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0536-4089
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZOYL PEROXIDE (BENZOYL PEROXIDE)	BENZOYL PEROXIDE	50 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
WATER		
EDETATE SO DIUM		
STEARETH-30		
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)		
DIISOPROPANOLAMINE		

Product Characteristics			
Color	WHITE (Off-White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-4089-56	1 in 1 CARTON		
1		42.5 g in 1 TUBE		

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)

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