

**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 sweating. 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**

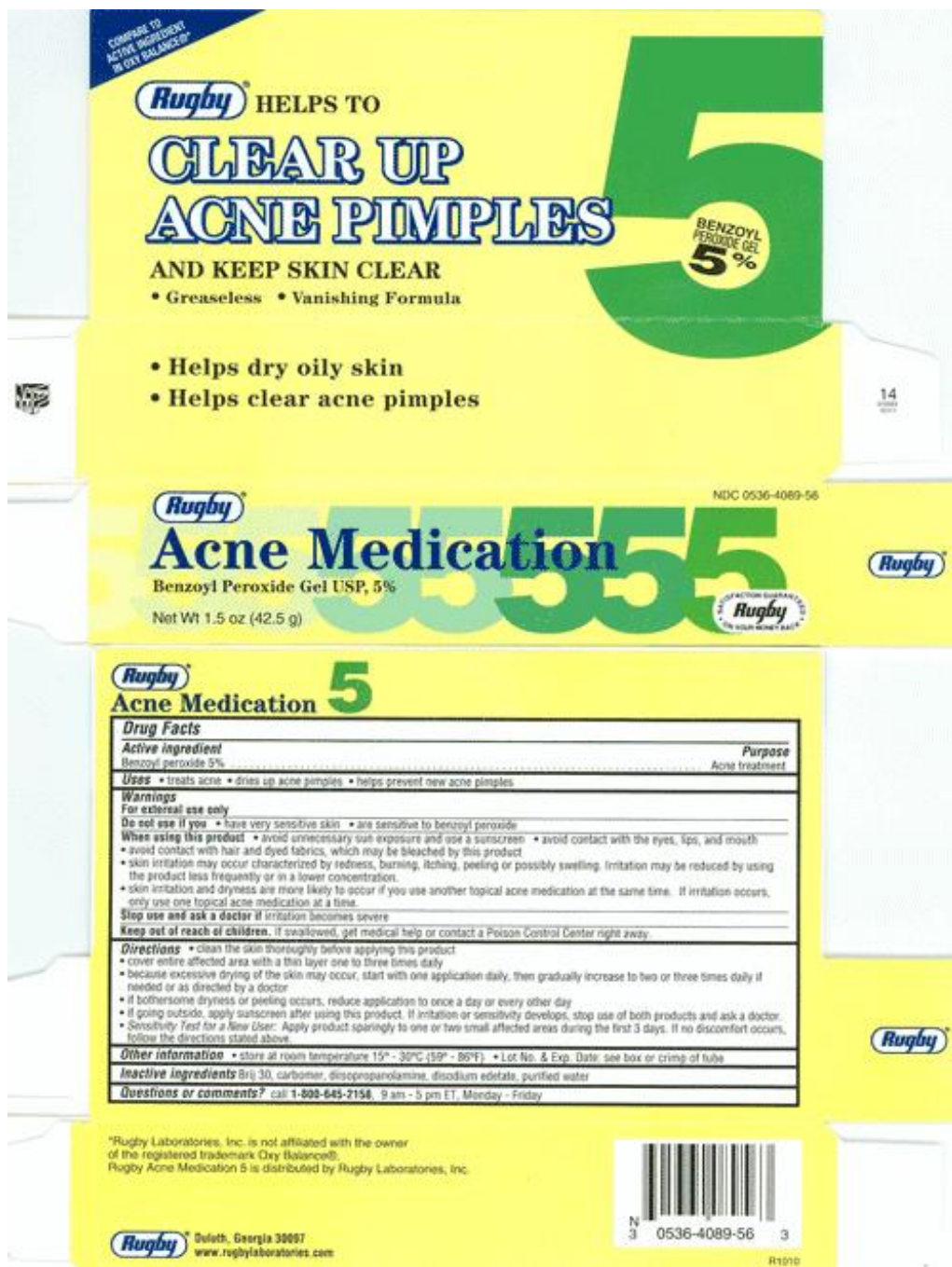
Store at room temperature 15 degrees to 30 degrees C (59 degrees to 86 degrees F)

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	Item Code (Source)	NDC:0536-4089
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 1 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE SODIUM (UNII: MP1J8420LU)	
STEARETH-30 (UNII: 5776GCL1DG)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
DIISOPROPANOLAMINE (UNII: 0W44HYL8T5)	

## Product Characteristics

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

## 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)

Revised: 1/2013

Rugby Laboratories