

ACNE MEDICATION 10- 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 10%

☐Purpose

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 sensitive skin or are sensitive to benzoyl peroxide

☐When using this product

- apply to affected areas only
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips and mouth
- this product may bleach hair or dyed fabrics
- with other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. Only one medication should be used unless directed by a physician
- skin irritation may occur characterized by redness, burning, itching, peeling or possible swelling

☐Stop 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 immediately.

Directions

- clean the skin thoroughly before applying
- cover the entire affected area with a thin layer 1 to 3 times daily
- because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 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 a sunscreen. Allow benzoyl peroxide to dry, then follow directions in the sunscreen labeling.
- Sensitivity Test for 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 degrees to 30 degrees C (59 degrees to 86 degrees F)
- Lot number & expiration date: See box or crimp of the tube

☐ ***Inactive ingredients***

Brij 30, carbomer, diisopropanolamine, edetate sodium, Purified water

Principal display panel

☐ 10% Benzoyl Peroxide Gel

BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	100 mg in 1 g
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
STEARETH-30 (UNII: 5776GCL1DG)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
DIISOPROPANOLAMINE (UNII: 0W44HYL8T5)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-4092-56	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

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