ACNE MED- benzoyl peroxide gel
Face Reality Skin Care, Llc

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.

Acne Med 5%

Drug Facts

Active Ingredient

Benzoyl Peroxide 2.5%

Purpose

For the treatment of Acne

Also Contains

Purified Water, Glycerin, Propylene Glycol, Carbomer, Sodium Hydroxide.

Uses

Adults and children 12 years and over:

For the treatment of acne.

For acne-prone or oily skin.

Warnings

For external use only. Avoid contact with eyes and eyelids. This product may cause irritation. Mild irritation may be reduced by using the product less frequently. If irritation becomes severe, discontinue use and consult a doctor.

Do not use

this medication if you have very sensitive skin or if you are sensitive to benzoly peroxide.

Keep out of reach of children.

Directions

Apply a thin layer on affected areas. Use for 15 to 30 minutes a day at first and increase wearing time gradually until medication can be tolerated at night. slight irritation is normal and temporary. If going outside, use a sunscreen. Allow the Acne Med to dry, then follow directions in the sunscreen labelling. If irritation or sensitivity develops, discontinue use of product and consult the Clinic.

Other Information

May bleach hair or fabrics. Store at room temperature. Keep away from heat or direct sunlight.

Package Labeling:

Drug Facts

Active Ingredient *Purpose*

Benzoyl Peroxide 5% . . . For the treatment of Acne

Also Contains

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Distributed by:
Face Reality, Inc. San Leandro, CA 94577
www.facerealityskincare.com

face reality™
SKINCARE

acne med
5%

2.0 FL OZ (30 mL)

ACNE MED

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70707-211
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	25 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70707-211-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	12/30/2016	
2	NDC:70707-211-02	60 mL in 1 TUBE; Type 0: Not a Combination Product	12/30/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	12/30/2016	

Labeler - Face Reality Skin Care, Llc (602958071)

Revised: 12/2017

Face Reality Skin Care, Llc