

CLEAR PROOF ACNE TREATMENT ACNE MEDICATION- benzoyl peroxide gel
Mary Kay Inc.

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.

Clear Proof Acne Treatment Gel
Drug Facts

Active ingredient:

Benzoyl Peroxide 5%

Purpose

Acne Medication

Uses

- for the management of acne
- dries up acne pimples
- helps prevent new acne pimples

Warnings

For external use only.

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

When using this product

- skin irritation and dryness is 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.
- 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.

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

- clean the skin thoroughly before applying this product
- cover the 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.

Other information

- store at 59° to 86° F
- expiration date on tube crimp

Inactive ingredients

aesculus hippocastanum (horse chestnut) seed extract, butylene glycol, carbomer, cucumis sativus (cucumber) fruit extract, diethylhexyl sodium sulfosuccinate, disodium EDTA, echinacea purpurea extract, glycerin, poloxamer 182, propylene glycol, silica, sodium hydroxide, water

Principal Display Panel - 28 g carton

clearproof

acne treatment gel

acne medication

5% benzoyl peroxide

1 OZ. NET WT./28 g

Mary Kay



acne treatment gel
095054

clearproof

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acne medication
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1 OZ. NET WT. / 28 g

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Drug Facts (continued)

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Stop use and seek a doctor if irritation becomes severe.
Keep out of reach of children. If the product is swallowed, get medical help or contact a Poison Control Center right away.

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MADE IN U.S.A.

Drug Facts (continued)

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Spanish translations inside /
Traducciones al español en el interior

Drug Facts

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20095056

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51531-9071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Poloxamer 182 (UNII: JX0HIX6OAG)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Docosate Sodium (UNII: F05Q2T2JA0)	
Edetate Disodium (UNII: 7FLD91C86K)	
Glycerin (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
Echinacea Purpurea (UNII: QI7G114Y98)	
Cucumber (UNII: YY7C30VXJT)	
Horse Chestnut (UNII: 3C18L6RJAZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51531-9071-1	1 in 1 CARTON	08/16/2016	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51531-9071-0	3 g in 1 TUBE; Type 0: Not a Combination Product	08/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	06/15/2012	

Labeler - Mary Kay Inc. (049994452)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Laboratories Inc.		001535103	manufacture(51531-9071)

