

## **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.*

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### **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



benzoyl peroxide gel

## Product Information

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

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	BENZOYL PEROXIDE	5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLOXAMER 182</b> (UNII: JX0HIX6OAG)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>ECHINACEA PURPUREA</b> (UNII: QI7G114Y98)	
<b>CUCUMBER</b> (UNII: YY7C30VXJT)	
<b>HORSE CHESTNUT</b> (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	M006	06/15/2012	

**Labeler -** Mary Kay Inc. (049994452)

## Establishment

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

Revised: 9/2022

Mary Kay Inc.