

**BLEMISH - benzoyl peroxide gel**  
**Kamins Dermatologics 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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**BLEMISH GEL 10% CONSUMER LABELING**

Active ingredients:

Benzoyl Peroxide: 10%

Purpose: Acne Treatment

Keep out of children's reach.

A unique oil-free, color-free benzoyl peroxide gel that helps to gently clear blemishes, blackheads and spots. Also contains our moisturizing Bio-Maple compound, which helps prevent skin from becoming excessively dry.

Uses

- Helps treat acne.
- Dries up acne pimples.
- Helps prevent new acne pimples.

Warnings

For external use only.

Do not use on

- broken skin.
  
- large areas of the body.

When using this product,

- Apply to affected areas only
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with eyes/eye area, lips, mouth and nostrils. If contact occurs, rinse thoroughly with water.
- This product may bleach hair or dyed fabrics.
- Using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. Only one drug should be used unless directed by a doctor.

Stop use and ask a doctor if too much skin irritation or sensitivity develops or increases.

If swallowed, seek medical assistance 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 too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2-3 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 medicated acne gel to dry, then follow directions on the

sunscreen labeling.

INACTIVE INGREDIENTS: water, alcohol denat., acer saccharum (maple isolate), disodium PEG-12 dimethicone sulfosuccinate, carbomer, sodium hydroxide, phenoxyethanol, caprylyl glycol, sorbic acid

B. KAMINS

BLEMISH GEL 10%

The image shows a large, solid green rectangular area. In the center of this area, the text "B. KAMINS" is written in a large, white, sans-serif font. Below "B. KAMINS", the word "laboratories" is written in a smaller, white, lowercase sans-serif font. The entire logo is centered horizontally and vertically within the green rectangle.

B. KAMINS  
laboratories



# Blemish Gel 10%

Benzoyl Peroxide 10%

Clear Skin

acne  
acné



30 ml / 1 fl. oz

30mL / 1.7 fl.oz

## **BLEMISH**

benzoyl peroxide gel

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63550-194
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	100 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ACER SACCHARUM SAP</b> (UNII: 75UOH57984)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63550-194-23	30 mL in 1 BOX		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333D	10/19/2010	

**Labeler** - Kamins Dermatologics Inc. (254050784)

**Registrant** - Kamins Dermatologics Inc. (254050784)

### Establishment

Name	Address	ID/FEI	Business Operations
Kamins Dermatologics Inc.		254050784	manufacture, pack, label

Revised: 10/2010

Kamins Dermatologics Inc.