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.

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

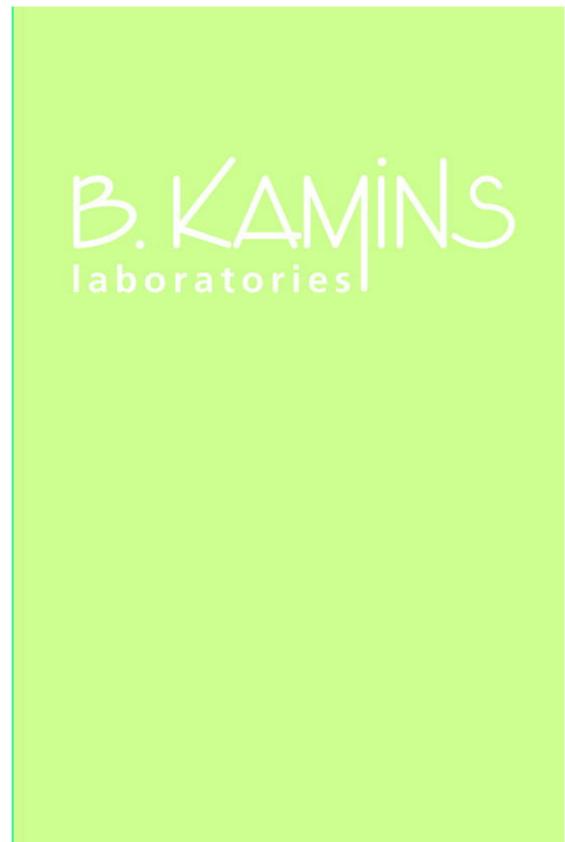
- Clean the skin thoroughly befor applying.
- Cover the entire affected area with a thin layer 1 to 3 times daily.
- because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2-3 times daily if needed or as directed by a doctor.
- If bothersome dryness 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%





BLEMISH benzoyl peroxide gel Product Information

Product Type	HUMAN OTC DRUG	Item Co	de (Source)	NDC:63	NDC:63550-194	
Route of Administratio	n TOPICAL					
Active Ingredient/A	ctive Mojety					
Active Ingredient/A	is of Strength	Strength				
Ingredient NameBasis of SBENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII: W9WZN9A0GM)BENZOYL PEROXIDE - PEROXIDE -					100 mg in 1 m	
Inactive Ingredients	S Ingredient Name					
	S	Strength				
WATER (UNII: 059QF0KC						
ACER SACCHARUM SAP	(UNII: 75UOH57984)					
DIMETHICO NE (UNII: 92)	RU3N3Y1O)					
SO DIUM HYDRO XIDE (U	NII: 55X04QC32I)					
PHENOXYETHANOL (UN						
CAPRYLYL GLYCOL (U	NII: 00YIU5438U)					
SORBIC ACID (UNII: X04	5WJ989B)					
Packaging						
	Package Description	Marketing	Start Date	Marketing	End Date	
# Item Code	· · · · · · · · · · · · · · · · · · ·	-				
	30 mL in 1 BOX					
# Item Code 1 NDC:63550-194-23						
1 NDC:63550-194-23	30 mL in 1 BOX					
	30 mL in 1 BOX	graph Citation	Marketing Star	rt Date Marke	ting End Date	

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.