

BREAKOUT CONTROL ACNE TREATMENT- benzoyl peroxide lotion
Bioelements, 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.

Breakout Control Acne treatment

Active ingredient	Purpose
Benzoyl Peroxide 5%	Acne treatment

Uses

For the treatment of acne

Helps prevent new acne blemishes

Keep out of reach of children. If swallowed get medical help or contact a poison control center right away

Stop use and ask a doctor if:

irritation becomes severe

Warnings

For external use only

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 only one topical acne medication at a time.
- Avoid unnecessary sun exposure and use a sunscreen
- Avoid contact with 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.
- Do not use if you:

Have very sensitive skin

Are sensitive to benzoyl peroxide

Directions

Cleanse the skin thoroughly before applying this product

cover the entire 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.

Inactive ingredients

Water (Aqua,Eau), Pentylene Glycol, Hydroxyethyl Acrylates/Sodium Acryloyldimethyl Taurate Copolymer, Squalene, Polysorbate 60, Aloe Bardadensis (Aloe) Leaf Juice powder, Phytic Acid,

Drug Facts Continued

Warnings Continued

Do not use if you:

- Have very sensitive skin
- Are sensitive to benzoyl peroxide

Stop use and ask a doctor if:

- Irritation becomes severe

Keep out of reach of children. If swallowed get medical help or contact poison control center right away.

Directions

- Cleanse 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.

Inactive ingredients

Water (Aqua, Eau), Pentylene Glycol, Hydroxyethyl Acrylates/Sodium Acryloyldimethyl Taurate Copolymer, Squalane, Polysorbate 60, Aloe Barbadensis (Aloe) Leaf Juice Powder, Phytic Acid, Phenoxyethanol, Potassium Sorbate, Disodium EDTA

Questions?
Call 1.800.433.6650 Monday - Friday 7:30AM - 4:30PM MST

BIOELEMENTS

PROFESSIONAL SKIN CARE

Breakout Control

Acne Treatment with Benzoyl Peroxide

- ✓ Dries and clears acne pimples
- ✓ Helps prevent new acne blemishes from forming
- ✓ Works invisibly under makeup or alone

About Bioelements

Chances are, if you have ever had a professional facial, you've experienced Bioelements. Since 1991, skin care specialists have been using our highly individualized formulas to treat the skin, target complexion concerns and discourage skin-aging. And, unlike ordinary skin care, each Bioelements product is a professionally created treatment designed to make a major difference in the appearance of your skin.

Drug Facts

Active ingredient	Purpose
Benzoyl Peroxide 5%	Acne treatment

Uses

- For the treatment of acne.
- Helps prevent new acne blemishes.

Warnings

- For external use only

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.

BIOELEMENTS®
Made in USA

Manufactured for Bioelements
3502 E. Boulder St.
Colorado Springs, CO 80909
Bioelements.com

29 mL / 1 Fl. Oz.

BIOELEMENTS PROFESSIONAL FORMULA INTEGRITY	✓ No artificial colorants
	✓ No synthetic fragrance
	✓ Not tested on animals
	✓ Contains natural botanicals

Bioelements

Breakout control

Emergency Blemish Lotion with Benzoyl Peroxide

29 mL/ 1 Fl. Oz.

Active ingredient: Benzoyl Peroxide 5%

Warnings: For external use only. Do not use on very sensitive skin. Keep away from eyes, lips and mouth. When using this product: Avoid unnecessary sun exposure and use a sunscreen. Using other topical acne medication at the same time or immediately following the use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. Keep out of reach of children. If swallowed get medical help or contact poison control center right away. May bleach hair or dyed fabric.

Directions: Cleansa skin thoroughly before applying. Cover the affected area with a thin layer 1 to 3 times a day. Because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 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 Breakout Control to dry, then follow directions on the sunscreen labeling. If sensitivity develops, discontinue use of both products and consult a doctor.

Manufactured for BIOELEMENTS®
3502 E. Boulder St.
Colorado Springs, CO 80909
Manufactured in USA / www.bioelements.com

SKU: PR205
ART: 120117

BIOELEMENTS

**Breakout
Control**

Emergency Blemish Lotion
with Benzoyl Peroxide

29 mL / 1 Fl. Oz.

BREAKOUT CONTROL ACNE TREATMENT

benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49825-124
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 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
SQUALENE (UNII: 7QWM220FJH)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FYTIC ACID (UNII: 7IGF0S7R8I)	
PHENOXYETHANOL (UNII: HIE49ZZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49825-124-02	1 in 1 BOX		
1	NDC:49825-124-01	29 mL in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333D	03/26/2012	

Labeler - Bioelements, Inc. (174813923)

Registrant - Bioelements, Inc. (174813923)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises Ltd		017701475	manufacture

Revised: 3/2012

Bioelements, Inc.