

**BREAKOUT CONTROL BIOELEMENTS- benzoyl peroxide cream
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

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 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,

Phenoxyethanol, Potassium Sorbate, Disodium EDTA.

Bioelements

Breakout control

5% benzoyl peroxide acne treatment

invisibly spot treats to clear acne breakouts

29 mL/ 1 Fl. Oz.

Active ingredient: Benzoyl Peroxide 5%

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. 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.

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

SKU: PR206
ART: 130528

BIOELEMENTS

**Breakout
Control**

5% benzoyl peroxide
acne treatment

29 mL / 1 Fl. Oz.



BREAKOUT CONTROL BIOELEMENTS

benzoyl peroxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49825-129
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 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	

HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
FYTIC ACID (UNII: 7IGF0S7R8I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49825-129-02	1 in 1 CARTON	06/14/2013	
1	NDC:49825-129-01	29 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	06/14/2013	

Labeler - Bioelements, Inc. (174813923)

Registrant - Bioelements, Inc. (174813923)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises Ltd		017701475	manufacture(49825-129)

Revised: 11/2019

Bioelements, Inc.