

ACNE TREATMENT- benzoyl peroxide gel

Vi-Jon

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.

10 % Benzoyl Peroxide Acne Medicated Gel

229

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne medication

Use

for the treatment of acne

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 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 possible 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 daily 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

carbomer, disodium EDTA, hydroxypropyl methylcellulose, laureth-4, sodium hydroxide, water
manufactured by Vi-Jon, Inc

St. Louis, MO 63114

229.001/229AD

principal display panel

mountain falls

Compart to Clean & Clear

for treat of acne

dermatologist tested

10% BENZOYL PEROXIDE acne treatment

maximum strength

NET WT 1 OZ (28 g)



"Compare to
Clear & Clear"

dermatologist
tested

for treatment
of acne

10% benzoyl
peroxide
acne
medication
maximum strength

NET WT 1 OZ (23 g)

ACNE TREATMENT

benzoyl peroxide gel

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0229
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)			BENZOYL PEROXIDE	1 mg in 1 g
Inactive Ingredients				
Ingredient Name				Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
LAURETH-4 (UNII: 6HQ855798J)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0229-10	1 in 1 PACKAGE	12/02/2011	
1		28 g in 1 TUBE; 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	12/02/2011	

Labeler - Vi-Jon (790752542)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(0869-0229)

Establishment			
Name	Address	ID/FEI	Business Operations
Remar		938028602	repack(0869-0229)