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, buring, itching, peeling or posible 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

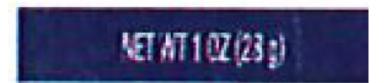
principal display panel

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)





10% benzoyl
peroxide
acne
medication
maximum strength



ACNE TREATMENT

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0229
Route of Administration	TOPICAL		

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
l	BENZO YL PERO XIDE (UNII: W9 WZN9 A0 GM) (BENZO YL PERO XIDE - UNII:W9 WZN9 A0 GM)	BENZOYL PEROXIDE	1 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)			
HYPROMELLOSES (UNII: 3NXW29 V3WO)			
LAURETH-4 (UNII: 6HQ855798J)			
SODIUM HYDRO XIDE (UNII: 55X04QC32I)			
WATER (UNII: 059QF0KO0R)			

1	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)

Revised: 5/2020 Vi-Jon