

ACNE TREATMENT- benzoyl peroxide gel Big Lots

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 229.001/229AC-AD

Active ingredients

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

Questions?

1-888-593-0593

This acne medication contains maximum strength benzoyl peroxide. The micronized benzoyl peroxide formula goes to work immediately, releasing the medicine deep into the pore where pimples begin.

*This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company, distributor of Clean & Clear Persa-Gel 10.

Manufacture for Big Lots by: Vi-Jon, inc.

8515 Page Avenue, St. Louis, MO 63114

Made in the USA with US and foreign components

229.001/229AD

principal display panel

SOUND BODY

COMPARE TO CLEAN & CLEAR PERSA-GEL 10*

10% BENZOYL PEROXIDE ACNE MEDICATION

MAXIMUM STRENGTH

NET WT. 1 OZ (28 g)



ACNE TREATMENT

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50594-229
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)			BENZOYL PEROXIDE	100 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:50594-229-10	1 in 1 CARTON	02/23/2016	
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	02/23/2016		

Labeler - Big Lots (017885351)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(50594-229)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(50594-229)

Establishment

Name	Address	ID/FEI	Business Operations
Remar Inc.		117825116	pack(50594-229)

