

BPO - benzoyl peroxide gel
Acella Pharmaceuticals, LLC

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.

BPO 4% Gel

Active Ingredient

Benzoyl Peroxide 4%

Purpose

Acne Medication

Use treats acne and helps prevent new acne blemishes from forming

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

For External Use only

Do not use if you have very sensitive skin or if you are sensitive to benzoyl peroxide

When using this product

- avoid unnecessary sun exposure and use sunscreen
- keep away from eyes, lips and mouth
- avoid contact with hair or dyed fabrics, including carpet and clothing which may be bleached by 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.
- skin irritation may occur, characterized by redness, burning, itching, peeling or possibly swelling. More frequent use or higher concentrations may aggravate such irritation. Mild irritation may be reduced by using the product less frequently or in a lower concentration.

Direction

- 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 application to once a day or every other day
- if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, discontinue use of product and consult a doctor

Inactive Ingredients

aloe barbadensis leaf juice, benzyl alcohol, cetareth-20, cetyl alcohol, dimethyl isisirbide, purified water, simethicone and stearyl alcohol.

NDC 42192-105-15

Drug Facts

Active Ingredients	Purpose
Benzoyl Peroxide 4%	Acne Medication

Use treats acne and helps prevent new acne blemishes from forming.

Warnings For external use only

Do not use if you have very sensitive skin or if you are sensitive to benzoyl peroxide.

When using this product • avoid unnecessary sun exposure and use sunscreen • keep away from eyes, lips and mouth • avoid contact with hair or dyed fabrics, including carpet and clothing which may be bleached by this product • skin irritation and dryness is more likely to occur if you use another topical acne medications, at the same time. If irritation occurs, only use one topical medication at a time • 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.

Stop use and ask a doctor if • irritation becomes severe, • if pregnant or breastfeeding. 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 application to once a day or every other day • if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, discontinue use of both products and consult a doctor.

Other information Store at controlled room temperature 15° - 30° C (59° - 86° F). Serious side effects associated with use of the product may be reported to 1-800-541-4802 or to the address listed on this carton.

Inactive ingredients also barbadensis leaf juice, benzyl alcohol, ceteareth-20, cetyl alcohol, dimethyl isosorbide, purified water, simethicone and stearyl alcohol.

Questions? 1-800-541-4802

Acella Pharmaceuticals, LLC • Alpharetta, GA 30009

This is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.



BPO 4% Gel

(benzoyl peroxide 4%)



AQUEOUS BASE GEL FOR TOPICAL USE

Net Wt
42.5 g (1.5 oz)



BPO

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42192-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9 WZN9 A0 GM) (BENZOYL PEROXIDE -	BENZOYL	4 mg in 100 mg

UNII:W9WZN9A0GM)		PEROXIDE	4 mg in 100 mg	
Inactive Ingredients				
Ingredient Name			Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-105-16	12 in 1 PACKAGE		
1		1 in 1 CARTON		
1		42500 mg in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333D	01/01/2009		

Labeler - Acella Pharmaceuticals, LLC (825380939)

Registrant - Ei Inc. (105803274)

Establishment

Name	Address	ID/FEI	Business Operations
Ei Inc.		105803274	manufacture(42192-105) , label(42192-105) , pack(42192-105)