

BPO 8% - 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 8% Gel

Active Ingredients

Benzoyl Peroxide 8%

Purpose

Acne Medication

Use

Treats acnes 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 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.
- 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.

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 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.

Other Information

Store at controlled room temperature 15° - 30°C (59° - 86°F).

Inactive Ingredients

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

Questions?

1-800-541-4802

Manufactured For:

Acella Pharmaceuticals, LLC
Alpharetta, GA 30005

Rev. 0718-01

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 42192-163-15

BPO 8% Gel
(8% benzoyl peroxide acne medication)

For Topical Use

Net Wt. 42.5 g (1.5 oz)

Acella Pharmaceuticals, LLC

NDC 42192-163-15

Drug Facts

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Benzoyl Peroxide 8%.....Acne Medication

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Manufactured For:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30005 rev. 1018-02

**BPO 8%
Gel**
(8% benzoyl peroxide acne medication)



FOR TOPICAL USE

Net Wt
42.5 g (1.5 oz)



BPO 8%

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42192-163
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	8 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-163-15	42500 mg in 1 TUBE; Type 0: Not a Combination Product	01/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/15/2019	

Labeler - Acella Pharmaceuticals LLC (825380939)

Revised: 2/2019

Acella Pharmaceuticals LLC