OC EIGHT - benzoyl peroxide gel
Biopelle, Inc.

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.

OC Eight Acne Mattifying Gel

Active Ingredient

Benzoyl peroxide 7%

Purpose

Acne Treatment

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, use only one topical acne medication at a time.
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the 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

- cleanse the skin thoroughly before applying
- cover the entire affected area with a thin layer 1 to 3 times a day
- because excessive drying of th skin may occur, start with 1 application daily, then gradually increase to 2 or 3 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 a sunscreen after using this product. Allow OC Eight Acne Mattifying Gel to dry, then follow directions in the sunscreen labeling. If irritation or sensitivity develops, stop use

of both products and ask a doctor.

Other Information

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

Inactive Ingredients

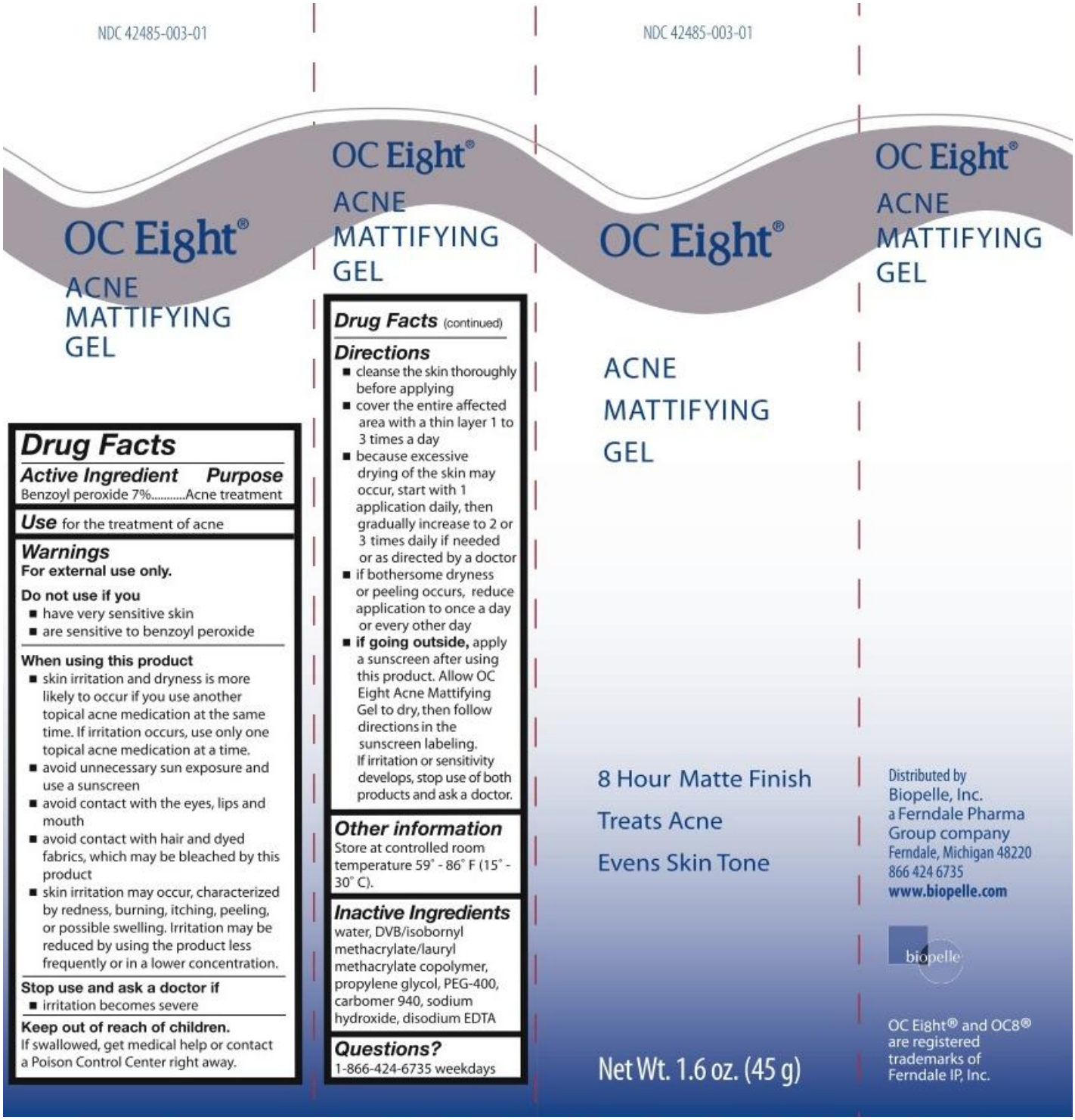
water, DVB/isobornyl methacrylate/lauryl methacrylate copolymer, propylene glycol, PEG-400, carbomer 940, sodium hydroxide, disodium EDTA

Questions?

1-866-424-6735 weekdays

Package Display
OC Eight®
Acne Mattifying Gel
Net Wt. 1.6 oz. (45 g)
NDC 42485-003-01

Distributed by Biopelle, Inc.
a Ferndale Pharma Group company
Ferndale, Michigan 48220
866-424-6735
www.biopelle.com



OC EIGHT

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42485-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	7 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42485-003-01	45 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333D	04/01/2011	

Labeler - Biopelle, Inc. (808158823)

Establishment

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories, Inc.		005320536	manufacture

Revised: 7/2011 Biopelle, Inc.