# BIBA ACNE- benzoyl peroxide gel Esthetic Underground, Inc.

-----

**Biba Acne** 

**DRUG FACTS:** 

### **Active Ingredient**

Benzoyl Peroxide 2.5%

### **Purpose**

Acne treatment

#### Uses

For the treatment of acne

### Warnings

For external use only

#### Do not use

- On sensitive skin
- If you are allergic to benzoyl peroxide

### Ask a doctor or pharmacist before use if you have severe acne

### When using this product

Skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time

- If irritation occurs, use one topical acne medication at a time
- Avoid contact with eyes, lips & 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 possibly swelling
- Irritation may be reduced by using the product less frequently or in a lower concentration
- Avoid unnecessary sun exposure and use sunscreen.

### Stop use and ask a doctor if

Irritation becomes severe.

### Keep out of reach of children

If swallowed, call a poison control center or get medical help 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 dryness of the skin may occur, start with one application daily, then gradually increase to two to three times daily if needed or as directed by a doctor
- If bothersome dryness of peeling occurs, reduce application to once a day every other day

### **Inactive Ingredients**

Water (Aqua), Glycerin, Cetearyl Alcohol, Cetearyl Glucoside, Pentylene Glycol, Propanediol, Caprylyl Glycol, Ethylhexylglycerin, Chlorphenesin, Carbomer, Xanthan Gum, Trisodium Ethylenediamine Disuccinate, Sodium Hydroxide, Citric Acid.

#### **Questions?**

01+ 310-770-5831

hello@bibalosangeles.com

DISTRIBUTED BY:

www.estheticunderground.com

Los Angeles CA 90036

#### PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

BIBA DE SOUSA LOS ANGELES

THE ACNE GEL

Net wt. 1.02 fl. oz. / 30 mL



### benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83834-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII: W9WZ N9A0GM)	BENZOYL PEROXIDE	2.5 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)	89.162 g in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	3 g in 100 mL		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	2.8 g in 100 mL		
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	0.7 g in 100 mL		
PENTYLENE GLYCOL (UNII: 50C1307PZG)	0.35 g in 100 mL		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.3 g in 100 mL		
PROPANEDIOL (UNII: 5965N8W85T)	0.3 g in 100 mL		
XANTHAN GUM (UNII: TTV12P4NEE)	0.3 g in 100 mL		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	0.15 g in 100 mL		
CHLORPHENESIN (UNII: 1670DAL4SZ)	0.15 g in 100 mL		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.1 g in 100 mL		
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	0.074 g in 100 mL		
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.064 g in 100 mL		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.05 g in 100 mL		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:83834- 001-01	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/15/2024	07/15/2026

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M006	07/15/2024	07/15/2026	

# **Labeler -** Esthetic Underground, Inc. (117323900)

## **Registrant - Product Society LLC (118666329)**

Establishment			
Name	Address	ID/FEI	Business Operations
Product Society LLC		118666329	manufacture(83834-001) , pack(83834-001) , label(83834-001)

Revised: 3/2025 Esthetic Underground, Inc.