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

Route of Administration

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

TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE -	BENZOYL PEROXIDE	2.5 g
UNII:W9WZ N9A0GM)	DENZOTE PEROXIDE	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			

l	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	01/02/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M006	01/02/2024	

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: 12/2023 Esthetic Underground, Inc.