

**GLYTONE ACNE BPO TREATMENT GEL- benzoyl peroxide gel**  
**Pierre Fabre USA Inc.**

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**GLYTONE Acne BPO Treatment Gel**

**Drug Facts**

**Purpose**

Acne Treatment

**Active Ingredient**

Benzoyl Peroxide 5%

**Use**

For the treatment of Acne.

Dries and clears acne blemishes and allows skin to heal.

Penetrates pores to eliminate most acne blemishes, blackheads and whiteheads.

Helps prevent the development of new acne blemishes, blackheads and whiteheads.

**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, only use one topical acne medication at a time.

avoid unnecessary sun exposure and use a sunscreen.

avoid contact with eyes. If eye contact occurs, rinse thoroughly with water.

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.

## **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 product.

Cover the affected area(s) 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 to three times daily or as directed by your physician.

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, stop use of both products and ask a doctor.

## **Other Information**

Store at room temperature of 68-77 F (22-25 C).

## **Inactive Ingredients**

Water (AQUA), PROPANEDIOL, DIMETHYL ISOSORBIDE, BUTYLENE GLYCOL, GLYCERIN, 1,2-HEXANEDIOL, ACRYLAMIDE/SODIUM ACRYLOYL-DIMETHYLTAURATE COPOLYMER, ISOHEXADECANE, HYDROXYACE-TOPHENONE, POLYSORBATE 80, POLYGLYCERYL-2 ISOSTEARATE, XANTHAN GUM, ENANTIA CHLORANTHA BARK EXTRACT, SODIUM CITRATE, TRISODIUM ETHYLENEDIAMINE DISUCCINATE, CITRIC ACID, DIETHYLHEXYL SODIUM SULFOSUCCINATE, CARBOMER, SODIUM HYDROXIDE, ETHYLHEXYL-GLYCERIN, CITRUS GRANDIS (GRAPEFRUIT) SEED EXTRACT, ECHINACEA ANGUSTIFOLIA EXTRACT, DIMETHICONE, ARCTIUM LAPPA ROOT EXTRACT, PHENOXYETHANOL, OLEANOLIC ACID, PEG-40 STEARATE, SILICA, SORBITAN STEARATE, TOCOPHEROL

## **Principal Display Panel - 60 mL**

GLYTONE

Acne BPO Treatment Gel

Acne Therapy

5% Micronized Benzoyl Peroxide

Non-Irritating Formula

60 mL/ 2 FL. OZ.

## Drug Facts

**Active Ingredient**      **Purpose**  
Benzoyl Peroxide 5% ..... Acne Treatment

**Use** For the treatment of acne.  
= Dries and clears acne blemishes and allows skin to heal. = Penetrates pores to eliminate most acne blemishes, blackheads and whiteheads.  
= Helps prevent the development of new acne blemishes, blackheads and whiteheads.

**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, only use one topical acne medication at a time. = avoid unnecessary sun exposure and use a sunscreen. = avoid contact with eyes. If eye contact occurs, rinse thoroughly with water. = 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.

**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 product. = Cover the affected area(s) 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 to three times daily or as directed by your physician. = 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, stop use of both products and ask a doctor.

**Other Information**  
Store at room temperature of 68-77°F (22-25°C).

## Drug Facts (continued)

**Inactive Ingredients**  
WATER (AQUA), PROPANEDIOL, DIMETHYL ISOSORBIDE, BUTYLENE GLYCOL, GLYCERIN, 1,2-HEXANEDIOL, ACRYLAMIDE/SODIUM ACRYLOYL-DIMETHYLTAURATE COPOLYMER, ISOHEXADECANE, HYDROXYACETOPHENONE, POLYSORBATE 80, POLYGLYCERYL-2 ISOSTEARATE, XANTHAN GUM, ENANTIA CHLORANTHA BARK EXTRACT, SODIUM CITRATE, TRISODIUM ETHYLENEDIAMINE DISUCCINATE, CITRIC ACID, DIETHYLHEXYL SODIUM SULFOSUCCINATE, CARBOMER, SODIUM HYDROXIDE, ETHYLHEXYLGLYCERIN, CITRUS GRANDIS (GRAPEFRUIT) SEED EXTRACT, ECHINACEA ANGUSTIFOLIA EXTRACT, DIMETHICONE, ARCTIUM LAPPA ROOT EXTRACT, PHENOXYETHANOL, OLEANDLIC ACID, PEG-40 STEARATE, SILICA, SORBITAN STEARATE, TOCOPHEROL.

# GLYTONE

Acne BPO  
Treatment Gel

ACNE THERAPY

5% Micronized  
Benzoyl Peroxide

NON-IRRITATING FORMULA

60 mL / 2 FL. OZ.



Pierre Fabre  
Dermo-Cosmétique

Distributed by:  
Pierre Fabre USA Inc.  
Parsippany, NJ 07054  
800-GLYTONE (459-8663)  
www.glytone.com

84361L

Acne BPO Treatment Gel features micronized time-released Benzoyl Peroxide to eliminate acne-causing bacteria, while a unique mattifying complex reduces the appearance of pore size and shine. This non-irritating medicated formula treats and prevents acne and reduces blemish inflammation without over-drying the skin.

Acné BPO Tratamiento Gel  
5% Micronizado de  
Peróxido de Benzoílo

El gel para el tratamiento del acné con BPO contiene peróxido de benzoílo micronizado de liberación prolongada para eliminar las bacterias que causan el acné y un exclusivo complejo matificante que reduce el aspecto del tamaño de los poros y el brillo. Esta fórmula medicinal no irritante trata y previene el acné, y reduce la inflamación del acné sin reseca la piel.

## GLYTONE ACNE BPO TREATMENT GEL

benzoyl peroxide gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64760-732
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	BENZOYL PEROXIDE	50 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>GRAPEFRUIT SEED OIL</b> (UNII: 598D944HOL)	

<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>PEG-40 STEARATE</b> (UNII: ECU18C66Q7)
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)
<b>ANHYDROUS DEXTROSE</b> (UNII: 5SL0G7R0OK)
<b>ARCTIUM LAPPA ROOT OIL</b> (UNII: 55DGS3F5YG)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>OLEANOLIC ACID</b> (UNII: 6SMK8R7TGJ)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0)
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)
<b>ANNICKIA CHLORANTHA BARK</b> (UNII: H70115MP4A)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)
<b>POLYGLYCERYL-2 ISOSTEARATE</b> (UNII: 7B80E71MQC)
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)
<b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22H34H9Q)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>ECHINACEA ANGUSTIFOLIA</b> (UNII: VB06AV5US8)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>CARBOMER 1342</b> (UNII: 809Y72KV36)
<b>SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S)</b> (UNII: 5F4963KLHS)
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85KORA)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)
<b>WATER</b> (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-732-01	1 in 1 CARTON	09/01/2021	01/31/2025
1		1 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	09/01/2021	01/31/2025

**Labeler** - Pierre Fabre USA Inc. (117196928)

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**Registrant** - Pierre Fabre USA Inc. (117196928)

Revised: 4/2024

Pierre Fabre USA Inc.