

**GLYTONE ACNE 3P TREATMENT GEL- benzoyl peroxide gel**  
**Pierre Fabre USA 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.*

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**Glytone Acne 3P Treatment Gel**

**Active Ingredient Purpose**

Benzoyl Peroxide 5% Acne Treatment

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**

**Do not use** if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

**When using this product**

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- 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 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 possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

**Stop use and ask a doctor if**

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- irritation becomes severe

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

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- 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 if needed or as directed by your 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, stop use of both products and ask a doctor.

## Other Information

### Other Information

Store at room temperature of 68-77°F (20-25°C).

### Inactive ingredients

Water, polyacrylamide, C13-14 Isoparaffin, PEG-8/SMDI Copolymer, Phenoxyethanol, Caprylyl Glycol, Laureth-7, Citric acid

<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ irritation becomes severe</li> </ul> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ Cleanse the skin thoroughly before applying product.</li> <li>■ Cover the affected area(s) with a thin layer one to three times daily.</li> <li>■ Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two to three times or as directed by your doctor.</li> <li>■ If bothersome dryness or peeling occurs, reduce application to once a day or every other day.</li> <li>■ If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.</li> </ul> <p><b>Other Information</b> Store at room temperature of 68-77° F (20-25° C).</p> <p><b>Inactive ingredients</b> WATER, POLYACRYLAMIDE, C13-14 ISOPARAFFIN, PEG-8/SMDI COPOLYMER, PHENOXYETHANOL, CAPRYLYL GLYCOL, LAURETH-7, CITRIC ACID</p>	<h1>GLYTONE</h1>	<p>Acne 3P® Treatment Gel is formulated with a patented time-released micronized Benzoyl Peroxide to eliminate acne-causing bacteria while minimizing potential irritation. This innovative hydro-gel formulation continues to fight acne throughout the day while maintaining skin's moisture and fending off dryness. Non-whitening matte finish. Suitable for all skin types.</p> <p>Acné 3P® Tratamiento Gel 5 % Micronizado de Peróxido de Benzoilo</p> <p>Acné 3P® Tratamiento Gel está formulado con un sistema patentado de liberación gradual micronizado de peróxido de benzoilo que elimina las bacterias que causan el acné y reduce al mínimo la irritación potencial. Esta formulación innovadora en hidro-gel combate el acné continuamente durante todo el día mientras mantiene la humedad de la piel y protege de la sequedad. Acabado mate no blanqueador. Adecuado para todo tipo de piel.</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient Purpose</b> Benzoyl Peroxide 5 %.....Acne Treatment</p> <p><b>Use</b> For the treatment of acne.</p> <ul style="list-style-type: none"> <li>■ Dries and clears acne blemishes and allows skin to heal.</li> <li>■ Penetrates pores to eliminate most acne blemishes, blackheads, and whiteheads.</li> <li>■ Helps prevent the development of new acne blemishes, blackheads, and whiteheads.</li> </ul> <p><b>Warnings</b> <b>For external use only.</b></p> <p><b>Do not use if you</b></p> <ul style="list-style-type: none"> <li>■ have very sensitive skin</li> <li>■ are sensitive to benzoyl peroxide</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ 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.</li> <li>■ avoid unnecessary sun exposure and use a sunscreen</li> <li>■ avoid contact with the eyes, lips, and mouth</li> <li>■ avoid contact with hair and dyed fabrics, which may be bleached by this product</li> <li>■ 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.</li> </ul>	
<p><b>ACNE THERAPY</b></p>		<p>5% Micronized Benzoyl Peroxide</p> <p>NON-IRRITATING FORMULA</p> <p>NET WT. 56.7 g / 2 OZ.</p>		 <p><b>Pierre Fabre</b> Derma-Cosmétique</p> <p>Distributed by: <b>Pierre Fabre USA, Inc.</b> Parsippany, NJ 07054 800-GLYTONE (459-8663) www.glytone.com</p> <p>83961L</p>

Glytone Acne 3P Treatment Gel  
5% micronized benzoyl peroxide  
non-irritating formula  
Net Wt. 56.7g / 2 oz.

# GLYTONE ACNE 3P TREATMENT GEL

benzoyl peroxide gel

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64760-704
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	2.8 g in 56.7 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
POLYETHYLENE GLYCOL 800 (UNII: UH6KR4953D)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
LAURETH-7 (UNII: Z95S6G8201)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-704-01	1 in 1 CARTON	10/15/2010	
1		56.7 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/15/2010	

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

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