

**GLYTONE ACNE TREATMENT MASK- sulfur cream**  
**GLYTONE ACNE CLARIFYING TREATMENT MASK- sulfur cream**  
**Pierre Fabre USA Inc.**

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**GLYTONE Acne Treatment Mask**

***Drug Facts***

***Active ingredient***

Sulfur 6.4%

***Purpose***

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**

**Flammable: Keep away from fire or flame**

**Flammable: Keep away from fire or flame.**

**Do not use on**

- broken skin
- large areas of the skin

**When using this product**

- apply only to areas with acne
- 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 contact with eyes. If eye contact occurs, flush thoroughly with water.

**Stop use and ask a doctor**

- if excessive skin irritation develops or increases.

**Keep out of reach of children.**

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

**Directions**

- Before first use, break the safety seal by twisting the inverted cap over the star-shaped seal.
- Cleanse the skin thoroughly before applying this mask.
- Apply a generous amount to the entire face and neck, or as directed by your physician.
- Avoid eyes, nostrils, and lips.
- Leave on skin for 20-25 minutes.
- Remove with lukewarm water in a gentle circular motion. Pat dry.
- Use one to three times a week, or as directed by your physician.

**Other information**

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

**Inactive Ingredients**

WATER, BENTONITE, ISOPROPYL ALCOHOL, KAOLIN, ZINC OXIDE, GLYCERIN, CALCIUM OXIDE, COCAMIDE MIPA, FRAGRANCE, METHYLPARABEN, SODIUM LAURYL SULFATE.

**Principal Display Panel - 85 g - Glytone Acne Treatment Mask Carton**

GLYTONE

Acne

Treatment

Mask

ACNE THERAPY

6.4% SULFUR

NET WT. 85 g / 3 OZ.

<p><b>Drug Facts</b> (continued)</p> <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>Before first use, break the safety seal by twisting the inverted cap over the star-shaped seal.</li> <li>Cleanse the skin thoroughly before applying this mask.</li> <li>Apply a generous amount to the entire face and neck, or as directed by your physician.</li> <li>Avoid eyes, nostrils, and lips.</li> <li>Leave on skin for 20-25 minutes.</li> <li>Remove with lukewarm water in a gentle circular motion. Pat dry.</li> <li>Use one to three times a week, or as directed by your physician.</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, BENTONITE, ISOPROPYL ALCOHOL, KAOLIN, ZINC OXIDE, GLYCERIN, CALCIUM OXIDE, COCAMIDE MIPA, FRAGRANCE, METHYLPARABEN, SODIUM LAURYL SULFATE.</p>	<h1>GLYTONE</h1>  <p>Acne Treatment Mask</p> <div style="background-color: #800000; color: white; padding: 5px; display: inline-block; margin: 10px 0;">ACNE THERAPY</div> <p>6.4% Sulfur</p>  <p>NET WT. 85 g / 3 OZ.</p>	<p>Acne Treatment Mask penetrates deep to reduce breakouts and soothe inflammation. It clears and minimizes pores, reduces surface oils and helps eliminate blackheads, whiteheads and pimples. Recommended for normal to oily skin.</p> <p>Mascarilla para Tratamiento contra Acné 6.4% Azufre</p> <p>Mascarilla para Tratamiento contra Acné penetra profundamente para reducir los brotes y aliviar la inflamación. Limpia y minimiza los poros, reduce la grasa de la superficie y ayuda a eliminar puntos negros, puntos blancos y espinillas. Recomendado parapiel normal a grasa.</p>	<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Sulfur 6.4%</td> <td>Acne Treatment</td> </tr> </tbody> </table> <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> For external use only.</p> <p><b>Flammable: Keep away from fire or flame.</b></p> <p><b>Do not use on</b></p> <ul style="list-style-type: none"> <li>broken skin</li> <li>large areas of the skin</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>apply only to areas with acne</li> <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 contact with the eyes. If eye contact occurs, flush thoroughly with water.</li> </ul> <p><b>Stop use and ask a doctor</b></p> <ul style="list-style-type: none"> <li>if excessive skin irritation develops or increases.</li> </ul>	Active ingredient	Purpose	Sulfur 6.4%	Acne Treatment
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Sulfur 6.4%	Acne Treatment						
 <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>							

## Principal Display Panel - 85 g - Glytone Acne Clarifying Treatment Mask Carton

GLYTONE

ACNE CLARIFYING TREATMENT MASK

ACNE THERAPY

6.4% SULFUR

1% GLYCOLIC ACID

1% LACTIC ACID

NET WT. 85 G / 3 OZ.

**Drug Facts**

**Active ingredient Purpose**  
Sulfur 6.4% 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.

**Flammability:** Keep away from fire or flame.

**Do not use on**  

- Broken skin
- Large areas of the skin

**When using this product**  

- Apply only to areas with acne
- 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 contact with the eyes. If eye contact occurs, flush thoroughly with water.

**Stop use and ask a doctor**  

- If excessive skin irritation develops or increases.

**Drug Facts (continued)**

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 this mask.
- Apply a generous amount to the entire face and neck, or as directed by your physician.
- Avoid eyes, nostrils, and lips. Leave on skin for 20-25 minutes.
- Remove with lukewarm water in a gentle circular motion. Pat dry.
- Cover the entire affected area with a thin layer one to three times daily.
- Reduce 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 physician.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

**Other information**  
Store at room temperature of 68-77°F (20-25°C)

**Inactive ingredients**  
WATER, BENTONITE, KAOLIN, GLYCERIN, PENTYLENE GLYCOL, GLYCERYL RICINOLEATE, STEARIC ACID, GLYCERYL STEARATE, GLYCOLIC ACID, POLYPERBATE 20, LEUCOMOSTOGENIN ROOT FERMENT FILTRATE, LACTIC ACID, 1,2-HEXANEDIOL, ALGAE BARBADENSIS LEAF JUICE POWDER, BISABOLIN, CAPRYLYL GLYCOL, CITRIC ACID, MENTHOL, LACTATE, SCORHA GLUCONATE, SODIUM HYDROXIDE, TRIPALININE

# GLYTONE

Acne Clarifying Treatment Mask

ACNE THERAPY

6.4% Sulfur  
1% Glycolic Acid  
1% Lactic Acid

NET WT. 85 g / 3 OZ.

Acne Clarifying Treatment Mask helps deep clean pores to fight existing breakouts while preventing new acne from forming. Formulated with 6.4% Sulfur, it quickly neutralizes acne bacteria and reduces excess oil to help control breakouts. Glycolic and Lactic Acids to help dissolve dead skin cells that can clog pores and fade dark spots. Experience a light cooling sensation that leaves skin feeling refreshed while Aloe and Bisabolol help reduce visible redness. Kaolin and Bentonite Clay provide a matte finish. This medicated mask promotes a visibly clear complexion while minimizing appearance of blemishes and pores.

La máscara de tratamiento aclarante para el acné ayuda a limpiar profundamente los poros para combatir las erupciones existentes y, al mismo tiempo, evitar que se forme acné nuevo. Formulada con 6.4% de azufre, neutraliza rápidamente las bacterias del acné y reduce el exceso de grasa para ayudar a controlar los brotes. Los ácidos glicólico y láctico ayudan a disolver las células muertas de la piel que pueden obstruir los poros y desvanecer las manchas oscuras. Experimente una sensación refrescante y ligera que deja la piel con una sensación de frescura, mientras que el aloe y el bisabolol ayudan a reducir el enrojecimiento visible. La arcilla de caolín y bentonita proporciona un acabado mate. Esta máscara medicinal promueve un cutis visiblemente claro y minimiza la aparición de imperfecciones y poros.

**Pierre Fabre**  
Derma-Cosmétique

Distributed by:  
Pierre Fabre USA Inc,  
Parsippany, NJ 07054  
800-GLYTONE (453-8663)  
www.glytone.com

8452L

## GLYTONE ACNE TREATMENT MASK

sulfur cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64760-710
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	64 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BENTONITE</b> (UNII: A3N5ZCN45C)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	

<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LIME (CALCIUM OXIDE)</b> (UNII: C7X2M0VWNH)	
<b>COCO MONOISOPROPANOLAMIDE</b> (UNII: 21X4Y0VTB1)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-710-01	1 in 1 CARTON	03/14/2018	
1		85 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 Drug	M006	03/14/2018	06/05/2024

## GLYTONE ACNE CLARIFYING TREATMENT MASK

sulfur cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64760-714
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII: 70FD1KFU70)	SULFUR	64 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>GLYCOLIC ACID</b> (UNII: 0WT12SX38S)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>LACTIC ACID LACTATE, L-</b> (UNII: 26T86KT372)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>MENTHYL LACTATE, (-)-</b> (UNII: 2BF9E65L7I)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BENTONITE</b> (UNII: A3N5ZCN45C)	

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE</b> (UNII: D2QHA03458)
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>BISABOLOL OXIDE A</b> (UNII: 16AE65F94Y)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)
<b>TROPOLONE</b> (UNII: 7L6DL16P1T)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>GLYCERYL RICINOLEATE</b> (UNII: ZUE0CEL42O)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-714-01	1 in 1 CARTON	06/23/2023	10/10/2024
1		85 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 Drug	M006	06/23/2023	10/10/2024

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

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