

**PROACTIV SKIN PURIFYING MASK- sulfur lotion**  
**Alchemee, LLC**

*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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**Proactiv Skin Purifying Mask**

**Drug Facts**

**Active ingredient**

Sulfur 6%

**Purpose**

Acne treatment

**Use**

for the management of acne

**Warnings**

**For external use only**

**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.
- apply only to areas with acne
- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

**Do not use on**

- broken skin
- large areas of the skin

**Keep out of reach of children.**

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

**Directions**

- *Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follows the directions stated below.
- clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer and rinse thoroughly one to three

times daily

- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day.

### ***Inactive ingredients***

water, kaolin, glycereth-26, linoleic acid, cetearyl alcohol, magnesium aluminum silicate, synthetic wax, cetareth-20, sodium lauroyl sarcosinate, linolenic acid, tocopheryl acetate, melaleuca alternifolia (tea tree) leaf oil, cymbopogon schoenanthus extract, geranium maculatum extract, hydrated silica, ethoxydiglycol, butylene glycol, phenoxyethanol, sodium sulfate, fragrance, titanium dioxide, zinc oxide, chromium hydroxide green

### ***Questions or comments?***

1-800-950-4695

Distributed by Alchemee LLC

Santa Monica, CA 90401

Made in the USA of Foreign and

Domestic Components

Questions? 1-800-950-4695 • [proactiv.com](http://proactiv.com)

Proactiv is a registered trademark of

Taro Pharmaceuticals U.S.A., Inc.

### **PRINCIPAL DISPLAY PANEL - 1 OZ. 28 g**

proactiv®

SKIN

PURIFYING

MASK

NET. WT. 1 OZ. (28 g)

sulfur acne medication

<p><b>Drug Facts</b></p> <p><b>Active ingredient Purpose</b> Sulfur 6%.....Acne treatment</p> <p><b>Use</b> for the management of acne</p> <p><b>Warnings</b> For external use only</p> <p><b>When using this product</b>  <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>apply only to areas with acne</li> <li>avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.</li> </ul> </p> <p><b>Do not use on</b> <ul style="list-style-type: none"> <li>broken skin</li> <li>large areas of the skin.</li> </ul> </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>Drug Facts</b> (continued)</p> <p>increase to two or three times daily if needed or as directed by a doctor  <ul style="list-style-type: none"> <li>if bothersome dryness or peeling occurs, reduce application to once a day or every other day.</li> </ul> </p> <p><b>Inactive ingredients</b> water, kaolin, glycereth-26, linoleic acid, cetearyl alcohol, magnesium aluminum silicate, synthetic wax, ceteareth-20, sodium lauroyl sarcosinate, linolenic acid, tocopheryl acetate, melaleuca alternifolia (tea tree) leaf oil, cymbopogon schoenanthus extract, geranium maculatum extract, hydrated silica, ethoxydiglycol, butylene glycol, phenoxyethanol, sodium sulfate, fragrance, titanium dioxide, zinc oxide, chromium hydroxide green</p> <p><b>Questions or comments?</b> 1-800-950-4695</p>	<p><b>proactiv.</b></p> <p><b>SKIN PURIFYING MASK</b></p> <p>NET. WT. 1 OZ. (28 g)</p>	<p>A potent deep-cleansing sulfur mask formulated to clear acne blemishes and help prevent new breakouts from forming. This soothing acne treatment helps to absorb excess oil. Antioxidant vitamins and naturally-derived botanicals help to soothe, condition, nourish, and hydrate the skin. Use the mask as part of your cleansing ritual to refine the appearance of pores, or as an overnight spot treatment to help clear emerging acne breakouts.</p>
<p><b>Directions</b> <i>Sensitivity Test for a New User.</i> Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below. <ul style="list-style-type: none"> <li>clean the skin thoroughly before applying this product</li> <li>cover the entire affected area with a thin layer and rinse thoroughly one to three times daily</li> <li>because excessive drying of the skin may occur, start with one application daily, then gradually</li> </ul> </p>	<p>Distributed by Alchemee LLC Santa Monica, CA 90401 Made in the USA of Foreign and Domestic Components Questions? 1-800-950-4695 • proactiv.com</p>		

<b>PROACTIV SKIN PURIFYING MASK</b>			
sulfur lotion			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11410-013
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)		SULFUR	6 g in 100 g
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
WATER (UNII: 059QF0KO0R)			
KAOLIN (UNII: 24H4NWX5CO)			
GLYCERETH-26 (UNII: NNE56F2N14)			
LINOLEIC ACID (UNII: 9KJL21T0QJ)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)			

<b>Synthetic Wax (1200 Mw)</b> (UNII: Q3Z4BCH099)
<b>Polyoxyl 20 Cetostearyl Ether</b> (UNII: YRC528SWJY)
<b>Sodium Lauroyl Sarcosinate</b> (UNII: 632GS99618)
<b>Linolenic Acid</b> (UNII: ORBV727H71)
<b>.alpha.-tocopherol Acetate</b> (UNII: 9E8X80D2L0)
<b>Tea Tree Oil</b> (UNII: VIF565UC2G)
<b>Cymbopogon Schoenanthus Top</b> (UNII: 9SJI1LW39W)
<b>Geranium Maculatum Root</b> (UNII: 93IXI5B6OJ)
<b>Hydrated Silica</b> (UNII: Y6O7T4G8P9)
<b>Diethylene Glycol Monoethyl Ether</b> (UNII: A1A1I8X02B)
<b>Sodium Sulfate</b> (UNII: OYPR65R21J)
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z)
<b>Chromium Hydroxide Green</b> (UNII: RV8FT8XF5R)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-013-00	1 in 1 BOX	12/31/2012	05/14/2019
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11410-013-05	1 in 1 BOX	12/31/2013	
2		85 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:11410-013-10	1 in 1 BOX	09/01/2019	
3		9 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:11410-013-02	1 in 1 BOX	12/31/2013	
4		28 g in 1 TUBE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	12/31/2012	

**Labeler** - Alchemee, LLC (080216357)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
VEE PAK, LLC		874763303	manufacture(11410-013)

## Establishment

Name	Address	ID/FEI	Business Operations
Apex International Mfg LLC		079110793	manufacture(11410-013)

Revised: 11/2022

Alchemee, LLC