

**PROACTIV REFINING MASK- sulfur cream**  
**THE PROACTIV COMPANY 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 Solution Refining 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**

- do not use this product more than three times per day.
- skin irritation and dryness are 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

**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**

- *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, follow the directions stated below.
- apply a small amount to dampened skin.
- 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, cetareth-20, sodium lauroyl sarcosinate, linolenic acid, tocopheryl acetate, tocopherol, butylene glycol, melaleuca

alternifolia (tea tree) leaf oil, cymbopogon schoenanthus extract, geranium maculatum extract, hydrated silica, ethoxydiglycol, methylparaben, ethylparaben, fragrance, titanium dioxide, zinc oxide

**Questions or comments?**

Within US **1-800-950-4695**

Distributed by The Proactiv Company LLC

100 N. Sepulveda Blvd.

El Segundo, CA 90245 • [proactiv.com](http://proactiv.com)

Made in the USA of Foreign and Domestic Components

Proactiv is a trademark of The Proactiv Company Sàrl.

**PRINCIPAL DISPLAY PANEL - 100 g Tube Label**

**proactiv®**

REFINING

MASK

3.5 OZ. 100 g

sulfur acne medication

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3.5 OZ. 100 g

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PAJNV1085

sulfur acne medication

**PROACTIV REFINING MASK**

sulfur cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11410-507
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Sulfur (UNII: 70FD1KFU70) (Sulfur - UNII:70FD1KFU70)	Sulfur	0.06 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
KAOLIN (UNII: 24H4NWX5CO)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
LINOLENIC ACID (UNII: 0RBV727H71)	
TEA TREE OIL (UNII: VIF565UC2G)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
ETHYL PARABEN (UNII: 14255EXE39)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Glycereth-26 (UNII: NNE56F2N14)	
Cymbopogon Schoenanthus Top (UNII: 9SJI1LW39W)	
Geranium Maculatum Root (UNII: 93IXI5B6OJ)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-507-36	100 g in 1 TUBE; Type 0: Not a Combination Product	12/01/1998	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	12/01/1998	

**Labeler** - THE PROACTIV COMPANY LLC (080216357)**Establishment**

Name	Address	ID/FEI	Business Operations
VEE PAK, LLC		874763303	manufacture(11410-507)