

PROACTIV REFINING MASK- sulfur cream
Guthy-Renker 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.

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

- using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.
- do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor.
- do not use on broken skin or large areas of the skin. Apply only to areas with acne.

Stop use and ask a doctor if irritation occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- for rinse off treatment, apply to dampened skin.
- leave on for 10 minutes.
- rinse with water.
- for leave on treatment, apply to affected area.
- leave on overnight.
- rinse off in the morning.
- use 2-3 times a week.
- **if going outside, use a sunscreen.**
- if bothersome dryness or peeling occurs, reduce application use.

Inactive ingredients

water (aqua), kaolin, glycereth-26, linoleic acid, cetearyl alcohol, magnesium aluminum silicate, zinc oxide, cetareth-20, sodium lauroyl sarcosinate, linolenic acid, cymbopogon schoenanthus extract, geranium maculatum extract, melaleuca alternifolia (tea tree) leaf oil, tocopherol, tocopheryl acetate, butylene glycol, hydrated silica, ethoxydiglycol, ethylparaben, methylparaben, fragrance (parfum), titanium dioxide (CI 77891)

Dist. by Guthy-Renker®

PO Box 14383, Palm Desert, CA 92255-4383

proactiv.com

PRINCIPAL DISPLAY PANEL - 70 g Tube Label

Rodan & Fields

proactiv®

SOLUTION

REFINING

MASK

deep cleans

helps to minimize the
appearance of pores

sulfur acne treatment

2.5 OZ. 70 g

Drug Facts

Active ingredient	Purpose
Sulfur 6%.....	Acne treatment

Use for the management of acne

Warnings

For external use only

When using this product

- 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.

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

As a mask: Apply to dampened skin, leave on for 10 minutes and rinse off with warm water. Can be used up to two to three times a week. If going outside, use an SPF 15 product or higher. If bothersome dryness or peeling occurs, reduce application use. Can be used as an overnight spot treatment.

Inactive ingredients water, kaolin, glycereth-26, linoleic acid, cetearyl alcohol, magnesium aluminum silicate, zinc oxide, cetearth-20, sodium lauroyl sarcosinate, linolenic acid, cymbopogon schoenanthus extract, geranium maculatum extract, melaleuca alternifolia (tea tree) leaf oil, tocopherol, tocopheryl acetate, butylene glycol, hydrated silica, ethoxydiglycol, ethylparaben, methylparaben, fragrance, titanium dioxide (CI 77891)

Questions or comments? Within US 1-800-950-4695

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Rodan & Fields
proactiv[®]
SOLUTION

REFINING MASK

deep cleans

helps to minimize the appearance of pores

sulfur acne treatment

2.5 OZ. 70 g

PROACTIV REFINING MASK

sulfur cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11410-507
Route of Administration	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: 059QF0KO0R)	
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 SARCO SINATE (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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-507-11	1 in 1 BOX		
1		28 g in 1 TUBE		
2	NDC:11410-507-17	48 g in 1 TUBE		
3	NDC:11410-507-21	1 in 1 BOX		
3		70 g in 1 TUBE		
4	NDC:11410-507-36	100 g in 1 TUBE		
5	NDC:11410-507-66	1 in 1 BOX		
5	NDC:11410-507-36	100 g in 1 TUBE		

Marketing Information

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

Labeler - Guthy-Renker LLC (608315453)