

## **CLARIFYING COLLOIDAL SULFUR MASK- sulfur cream**

**Dr. Dennis Gross Skincare, 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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### **Clarifying Colloidal Sulfur Mask**

#### **DRUG FACTS**

##### **Active Ingredient**

*Colloidal Sulfur 5.0%*

##### **Purpose**

*Acne Treatment*

##### **Indications**

- for the treatment and management of acne
- penetrates pore to eliminate most acne blemishes and blackheads
- helps prevent development of new acne blemishes and blackheads

##### **Warnings**

*For external use only*

##### **When using this product**

- do not get into eyes
- do not use on broken skin
- using topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used until directed by a doctor

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

##### **Directions**

- cleanse the skin thoroughly before applying
- apply a thin layer to the affected area 1-3 times daily. Leave on for at least 10 minutes, then rinse.
- for AM use as a mattifier under makeup, apply a tiny amount and work into skin until it disappears
- for PM use as a mask 2-3x per week or as needed, apply a thicker layer, wear overnight & wash off in morning
- suitable for use on face, chest, and back
- if bothersome dryness occurs, reduce application to once a day or every other day

##### **Inactive ingredients**

Allantoin, Aloe Barbadensis Leaf Juice, Bentonite, Bisabolol, Butylene Glycol, Carthamus Tinctorius (Safflower) Seed Oil, Cetearyl Alcohol, Ethylhexylglycerin, Farnesol, Glycerin, Glyceryl Stearate, Glycine Soja (Soybean) Oil, Glycyrrhiza Glabra (Licorice) Root Extract, Kaolin, Opuntia Tuna Flower/Stem Extract, PEG-100 Stearate, Phenoxyethanol, Phenylethyl Resorcinol, Retinol, Rosmarinus

Officinalis (Rosemary) Leaf Oil, Salix Alba (Willow) Bark Extract, Sodium PCA, Tocopheryl Acetate, Water (Aqua), Zinc Oxide

**PRINCIPAL DISPLAY PANEL - 50g Jar Carton**

ACNE  
SOLUTIONS  
SKINCARE

**clarifying colloidal  
sulfur mask**

acne medication

Net Wt 1.7oz/50g e

Dr Dennis Gross

ACNE  
SOLUTIONS



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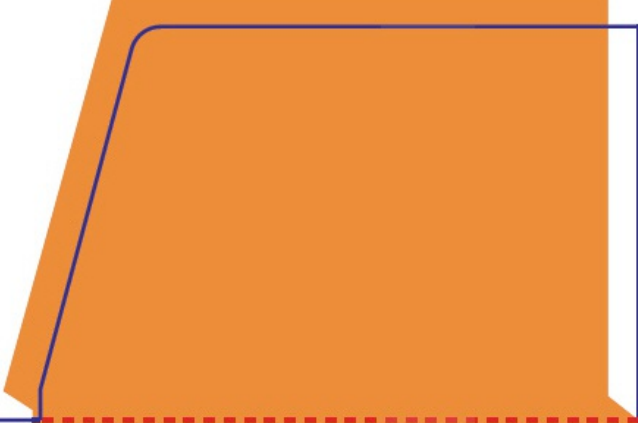
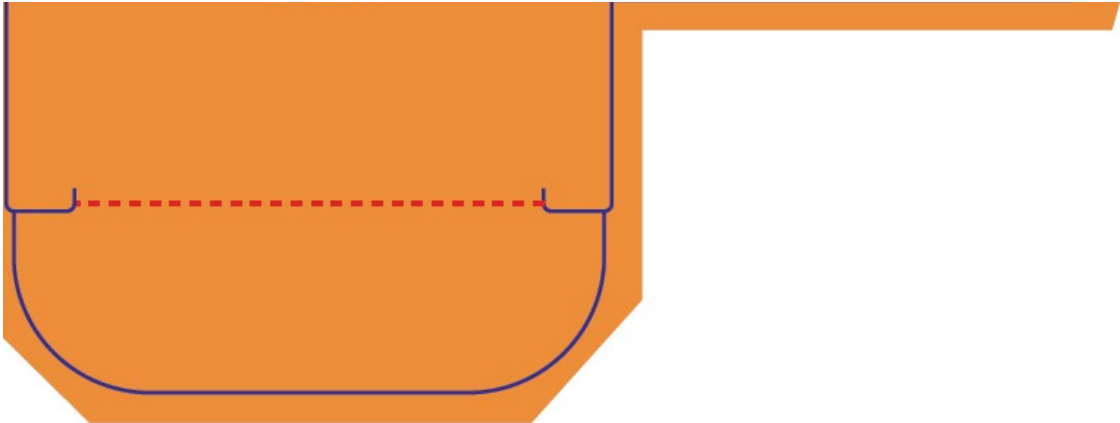


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◀ Continued

**What It Is:**

A clinical anti-aging mask that uses colloidal sulfur and bentonite to help reduce enlarged pores, blackheads, breakouts, and absorb excess oil.

**Why You Need It:**

You're looking for a non-drying, soothing formula to treat enlarged pores, which can age the appearance of skin. May be used as a targeted mattifying primer under makeup or as an overnight treatment mask.

**How To Use It:**

Apply to clean dry skin. For AM use as a pore-minimizing mattifying primer under makeup, apply a tiny amount to targeted area and work into the skin until it disappears. For PM use as a deeper treatment, apply a thicker layer to targeted area and wear overnight. Wash off in the morning

# CLARIFYING COLLOIDAL SULFUR MASK

sulfur cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58633-269
<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	50 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Kaolin</b> (UNII: 24H4NWX5CO)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>PEG-100 Stearate</b> (UNII: YD01N1999R)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z)	
<b>Bentonite</b> (UNII: A3N5ZCN45C)	
<b>Safflower Oil</b> (UNII: 65UEH262IS)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Opuntia Tuna Flowering Top</b> (UNII: R4AS8333O2)	
<b>Allantoin</b> (UNII: 344S277G0Z)	
<b>Levomenol</b> (UNII: 24WE03BX2T)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>Salix Alba Bark</b> (UNII: 205MXS71H7)	
<b>Sodium Pyrrolidone Carboxylate</b> (UNII: 469OTG57A2)	
<b>Phenylethyl Resorcinol</b> (UNII: G37UFG162O)	
<b>Glycyrrhiza Glabra</b> (UNII: 2788Z9758H)	
<b>Rosemary Oil</b> (UNII: 8LGU7VM393)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	
<b>Soybean Oil</b> (UNII: 241ATL177A)	
<b>Farnesol</b> (UNII: EB41QIU6JL)	
<b>Retinol</b> (UNII: G2SH0XKK91)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58633-269-10	1 in 1 CARTON		
1		50 g in 1 JAR		
2	NDC:58633-269-50	15 g in 1 JAR		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	08/01/2012	

**Labeler** - Dr. Dennis Gross Skincare, LLC (008190808)

## Establishment

Name	Address	ID/FEI	Business Operations
Phyto genX		010297942	MANUFACTURE(58633-269) , PACK(58633-269)

Revised: 7/2013

Dr. Dennis Gross Skincare, LLC