

AMINO MASK BIOELEMENTS- sulfur cream

Bioelements

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.

Amino Mask

Active ingredient	Purpose
Sulfur 5%	Acne treatment

Use

For the treatment of acne

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

When using this product: skin irritation and dryness is more likely to occur if you use another topical medication at the same time. If irritation occurs only use one topical acne medication at a time. Apply only to areas with acne.

Warnings

For external use only

Do not use on: Broken skin, large areas of the skin. Stop use and ask a doctor: if irritation occurs or gets worse. Do not get into eyes.

Directions

Cleanse the Skin thoroughly before applying this product. Cover the entire affected area with a thin layer and let dry 15 minutes then rinse well. Use twice a week. Because excessive drying of the skin may occur, start with one application, then gradually increase to two times a week if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application or discontinue use.

Inactive ingredients

Water (Aqua) (Eau), Kaolin, Caprylic/Capric Triglyceride, Glycerin, Cetearyl Alcohol, Cetareth-20, Glyceryl Stearate, PEG-100 Stearate, Dipotassium Glycyrrhizate, Lactic Acid, Bentonite, Chondrus Crispus (Carrageenan), Titanium Dioxide (CI 77891), Lavendula Angustifolia (Lavender) Oil, Camellia Sinensis (Green Tea) Leaf Extract, Vitis Vinifera (Grape) Fruit Extract, Actinidia Chinensis (Kiwi) Extract, Mel (Honey) Extract (Miel Extrait de Miel), Niacinamide, Biotin, Panthenol, Allantoin, Pyroxidine HCL, Hydrolyzed Soy Protein, Phenoxyethanol, Ethylhexylglycerin.

Bioelements

Acne Clearing System

Amino Mask

5% sulfur acne treatment mask with lactic acid

Treats acne breakouts and allows skin to heal

73 mL / 2.5 Fl. Oz.

Outer layer

<p>Drug Facts</p> <p>Active ingredient Sulfur 5% Purpose Acne treatment</p> <p>Use • For the treatment of acne.</p> <p>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 medication at a time.</p>		<p>Drug Facts (continued)</p> <p>Warnings (continued) Apply only to areas with acne. Do not use on: Broken skin, large areas of the skin. Stop use and ask a doctor: if skin irritation occurs or gets worse. Do not get into eyes. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.</p> <p>See inner label for additional Drug Facts</p>	<p>BIOELEMENTS PROFESSIONAL SKIN CARE</p> <p>Amino Mask® 5% sulfur acne treatment mask with lactic acid</p> <p>118 mL / 4 Fl. Oz.</p>
<p><small>Peel here</small></p>		<p>BIOELEMENTS® 3502 E. Boulder St. Colorado Springs, CO 80909 Manufactured for Bioelements Made in USA Bioelements.com</p> <p>8 36490 00298 5 SKU: AL104 / ART: 140521</p>	

=UV (peelable part of label)

Inner layer

<p>Drug Facts (continued)</p> <p>Directions Cleanse the skin thoroughly before applying this product. Cover the entire affected area with a thin layer and let dry 15 minutes, then rinse well. Use twice a week. Because excessive drying of the skin may occur, start with one application, then gradually increase to two times a week if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application or discontinue use.</p> <p>Inactive ingredients Water (Aqua, Eau), Kaolin, Caprylic/Capric Triglyceride, Glycerin, Cetearyl Alcohol, Ceteareth-20, Glyceryl Stearate, PEG-100 Stearate, Dipotassium Glycyrrhizate, Lactic Acid, Bentonite, Chondrus Crispus (Carrageenan), Titanium Dioxide (CI77891), Lavandula Angustifolia (Lavender) Oil, Camellia Sinensis (Green Tea) Leaf Extract, Vitis Vinifera (Grape) Fruit Extract, Actinidia Chinensis (Kiwi) Extract, Honey (Mel) Extract (Miel Extrait de miel), Niacinamide, Biotin, Panthenol, Allantoin, Pyridoxine HCl, Hydrolyzed Soy Protein, Phenoxethanol, Ethylhexylglycerin</p> <p>Questions? Call 1.800.433.6650 Monday - Friday 7:30AM - 4:30PM MST</p>	
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Active ingredient: Sulfur 5%

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BIOELEMENTS®
Made in USA

Manufactured for Bioelements
3502 E. Boulder St. Colorado Springs, CO 80909

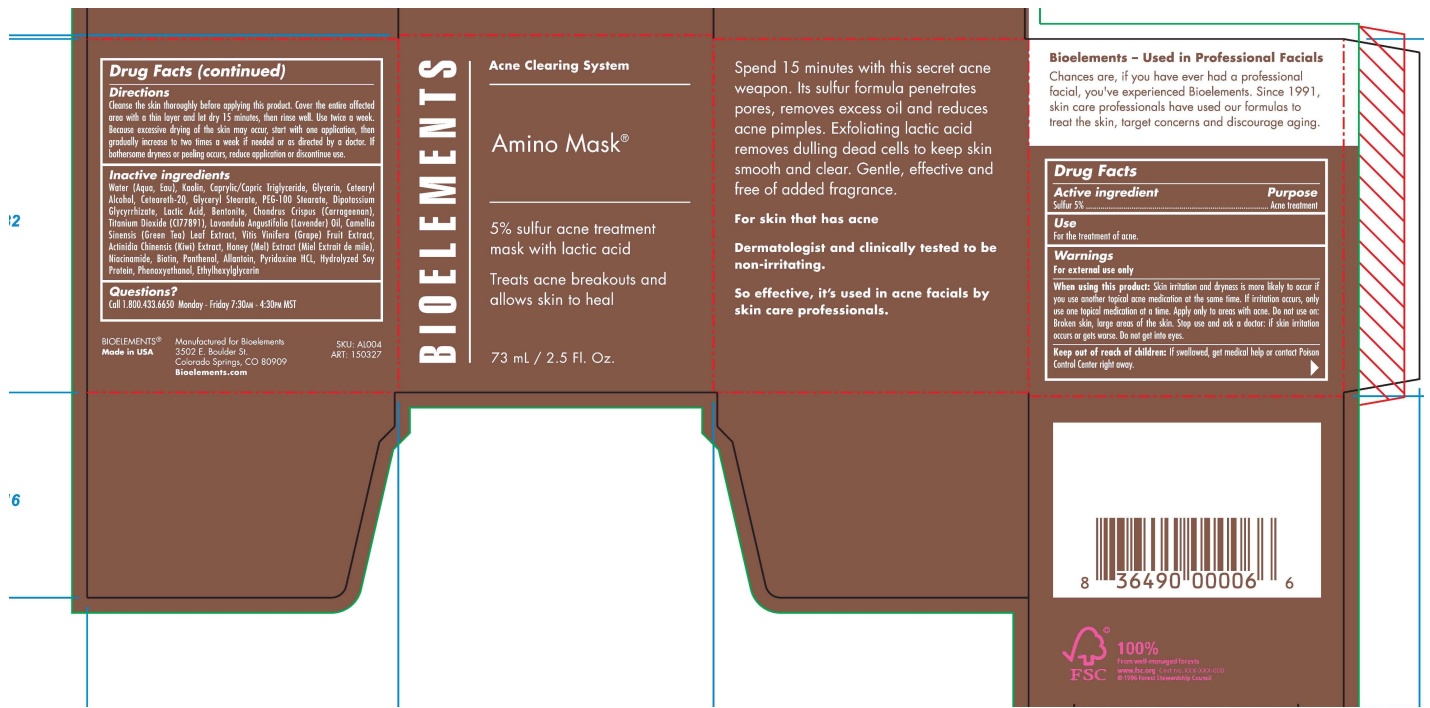
Bioelements.com
SKU: AL004 / ART: 130524

BIOELEMENTS

Amino Mask®

5% Sulfur Acne Treatment Mask with Lactic Acid

73 mL / 2.5 Fl. Oz.



AMINO MASK BIOELEMENTS

sulfur cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49825-128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
KAOLIN (UNII: 24H4NWX5CO)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
LACTIC ACID (UNII: 33X04XA5AT)	
BENTONITE (UNII: A3N5ZCN45C)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
WINE GRAPE (UNII: 3GOV20705G)	
KIWI FRUIT (UNII: 71ES77LGJC)	
HONEY (UNII: Y9H1V576FH)	
NIACINAMIDE (UNII: 25X51I8RD4)	
BIOTIN (UNII: 6SO6U10H04)	
PANTHENOL (UNII: WV9CM0O67Z)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49825-128-02	1 in 1 BOX	06/14/2013	
1	NDC:49825-128-01	73 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:49825-128-04	1 in 1 BOX	06/14/2013	
2	NDC:49825-128-03	118 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/14/2013	

Labeler - Bioelements (174813923)

Registrant - Bioelements (174813923)

Establishment

Name	Address	ID/FEI	Business Operations
Neutraderm, Inc.		146224444	manufacture(49825-128)