

BIOELEMENTS AMINO MASK- 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 ingredients	Purpose
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Sulfur 5%	Acne treatment
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Uses

For the management of acne

Helps prevent acne pimples (and/or acne blemishes, blackheads, whiteheads)

Keep out of reach of children

Stop use and ask a doctor

If skin irritation occurs or gets worse

Do not get into eyes

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.

Apply only to areas with acne

Do not use on:

- Broken Skin

- Large areas of the skin

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

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, Cetearth-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.

Drug Facts (continued)

Inactive ingredients
Water (Aqua) (Eau), Kaolin, Caprylic/Capric Triglyceride, Glycerin, Cetearyl Alcohol, Ceteareth-20, Glyceryl Stearate, PEG-100 Stearate, Dipotassium Glycyrrhizinate, Lactic Acid, Benzoin, Chandras Crispus (Carrageenan), Titanium Dioxide (CI 77891), Lavandula Angustifolia (Lavender) Oil, Camellia Sinensis (Green Tea) Leaf Extract, Vitis Vinifera (Grape) Fruit Extract, Actinidia Chinensis (Kiwi) Extract, Mal (Fruity) Extract (Malt Extract de mûle), Miconazole, Biotin, Panthenol, Allantoin, Pyroxidone HCl, Hydrolyzed Soy Protein, Phenoxyethanol, Ethylhexylglycerin

Questions?
Call 1.800.423.6650 Monday - Friday 7:30am - 4:30pm MST

BIOELEMENTS

ACNE CLEARING SYSTEM

PROFESSIONAL SKIN CARE

Amino Mask®

Sulfur Acne Treatment Mask with Lactic Acid

73 mL / 2.5 Fl. Oz.

- ✓ Unclogs pores
- ✓ Helps clear acne blemishes
- ✓ Allows skin to heal
- ✓ Controls excess oils

A highly active treatment power-packed with acne-fighting ingredients, Amino Mask unclogs pores, clears blemishes, controls oil and helps heal skin. Fragrance-free.

Drug Facts

Active ingredient	Purpose
Sulfur 5%	Acne treatment

Uses

- For the management of acne.
- Helps prevent acne pimples (and/or acne blemishes, blackheads, whiteheads)

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. • Apply only to areas with acne. Do not use on broken skin or 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.

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.

BIOELEMENTS®
Made in USA
Manufactured for Bioelements
3502 E. Boulder St.
Colorado Springs, CO 80909
Bioelements.com

SKU: AL004
ARE: 110825

Bioelements

Amino Mask (R)

Sulfur Acne Treatment Mask with Lactic Acid

73 mL / 2.5 Fl. Oz.

Active ingredient: Sulfur 5% (for the treatment 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 medication at a time. • Apply only to areas with acne. Do not use on broken skin or 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.

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.

BIOELEMENTS

Amino Mask®

Sulfur Acne Treatment Mask with Lactic Acid

73 mL / 2.5 Fl. Oz.

BIOELEMENTS®
Made in USA
Manufactured for Bioelements
3502 E. Boulder St. Colorado Springs, CO 80909
Bioelements.com
SKU: AL004 / ARE: 110729

BIOELEMENTS AMINO MASK

sulfur cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49825-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
KAOLIN (UNII: 24H4NWX5CO)	
CAPRYLIC/CAPRIC ACID (UNII: DI775RT244)	
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:49825-123-02	1 in 1 BOX		
1	NDC:49825-123-01	73 mL in 1 JAR		
2	NDC:49825-123-04	1 in 1 BOX		
2	NDC:49825-123-03	118 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	04/26/2012	

Labeler - Bioelements (174813923)

Registrant - Bioelements (174813923)

Establishment

Name	Address	ID/FEI	Business Operations
Neutraderm, Inc.		146224444	manufacture

Revised: 4/2012

Bioelements