

MDACNE CUSTOMIZED CREAM (SULFUR)- sulfur 3% cream
MDalgorithms Inc.

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.

DRUG FACTS:

Active Ingredient:

Sulfur 3.0%

Acne Treatment

Indications: ■ For the treatment of Acne. ■

Clears up acne pimples and blemishes, and allows skin to heal. Helps prevent new pimples and blemishes from forming.

Warnings For external use only

Do not use on broken skin or large areas of the skin. 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 acne medication at one time. ■ apply only to areas with acne.

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

If pregnant or breast feeding, ask

a health professional before use.

Directions: ■ clean the skin thoroughly before applying this product. ■ cover the entire affected area with a thin layer 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 directed by a doctor. ■ if bothersome dryness or peeling occurs reduce application to once a day or every other day.

Other Ingredients: Aqua (Deionized Water), Azelaic Acid, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Extract, Caprylyl Glycol, Cetearyl Alcohol, Chamomilla Recutita (Chamomile) Extract, Cucumis Sativus

(Cucumber) Extract, Dimethicone, Glycerin, Glycyrrhiza Glabra (Licorice) Extract, Hamamelis Virginiana (Witch Hazel), Hexylene Glycol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Magnesium Aluminum Silicate, Niacinamide, Olea Europaea (Olive) Oil, Parfum (Fragrance), PEG-150 Distearate, Phenoxyethanol, Polysorbate-80, Potassium Sorbate, Steareth-2, Steareth-20, Tetrasodium EDTA, Thymus Vulgaris (Thyme) Extract, Tocopherol (Vitamin E), Zemea (Corn) Propanediol.

Questions? Dist. by Mdalgorithms Inc. San Francisco, CA 94104. Manufactured in the USA. For customer support contact us at support@mdacne.com

Package Label

MDacne

Customized

Treatment

Cream

Night

Dermatologist Tested

Sulfur 3.0%

0.5 Oz | 15 mL

MDacne

Customized
Treatment
Cream

Night

Dermatologist Tested
Sulfur 3.0%
0.5 Oz. | 15 mL

DRUG FACTS:

Active Ingredient:

Sulfur 3.0% Acne Treatment

Indications: ■ For the treatment of acne. ■ Clears up acne pimples and blemishes, and allows skin to heal. Helps prevent new pimples and blemishes from forming.

Warnings: For external use only.

Do not use on broken skin or large areas of the skin. 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 acne medication at a time. ■ apply only to areas with acne.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. **If pregnant or breast-feeding,** ask a health professional before use.

Directions: ■ clean the skin thoroughly before applying this product. ■ cover the entire affected area with a thin layer 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.

Other Ingredients: Aqua (Deionized Water), Azelaic Acid, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Extract, Caprylyl Glycol, Cetearyl Alcohol, Chamomilla Recutita (Chamomile) Extract, Cucumis Sativus (Cucumber) Extract, Dimethicone, Glycerin, Glycyrrhiza Glabra (Licorice) Extract, Hamamelis Virginiana (Witch Hazel), Hexylene Glycol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Magnesium Aluminum Silicate, Niacinamide, Olea Europaea (Olive) Oil, Parfum (Fragrance), PEG-150 Distearate, Phenoxyethanol, Polysorbate-80, Potassium Sorbate, Steareth-2, Steareth-20, Tetrasodium EDTA, Thymus Vulgaris (Thyme) Extract, Tocopherol (Vitamin E), Zemea (Corn) Propanediol.

Questions? Dist. by Mdalgorithms Inc. San Francisco, CA 94104. Manufactured in the USA. For customer support contact us at support@mdacne.com

res

MDACNE CUSTOMIZED CREAM (SULFUR)

sulfur 3% cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71804-400 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) | SULFUR | 3 mg in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| WATER (UNII: 059QF0KO0R) | |
| AZELAIC ACID (UNII: F2VW3D43YT) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| CHAMOMILE (UNII: FGL3685T2X) | |
| CUCUMBER (UNII: YY7C30VXJT) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) | |
| WITCH HAZEL (UNII: 101I4J0U34) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4) | |
| MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) | |
| NIACINAMIDE (UNII: 25X51I8RD4) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |
| PEG-150 DISTEARATE (UNII: 6F36Q0I0AC) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| STEARETH-2 (UNII: V56DFE46J5) | |
| STEARETH-20 (UNII: L0Q8IK9E08) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |
| THYME (UNII: CW6570BU4N) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |
| CORN (UNII: 0N8672707O) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:71804-400-01 | 15 mL in 1 TUBE; Type 0: Not a Combination Product | 10/07/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333D | 10/07/2020 | |

Labeler - MDalgorithms Inc. (080479826)

Registrant - MDalgorithms Inc. (080479826)

Revised: 2/2022

MDalgorithms Inc.