

NATURASIL MITE BE GONE- sulfur cream
Nature's Innovation, Inc

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Mite• B• Gone Topical Mite and Multi-Purpose Itch Cream

Drug Facts

Active Ingredients:

Sulfur 1X HPUS

The letters HPUS indicate the component(s) in this product is (are) officially monographed in the Homeopathic Pharmacopeia of the United States.

Purpose:

Mite Symptom Relief

Uses: Symptomatic treatment of mite infections.

Warnings: For external use only. Ask a doctor before use if pregnant or nursing. Avoid using near eyes, mouth or mucous membranes. If eye contact occurs, rinse thoroughly with water and consult a doctor.

Keep out of reach of children. Do not use if tamper evident seal is broken. In case of ingestion call Poison Control Center hotline immediately at 1-800-222-1222.

Directions: Cleanse skin thoroughly before applying. Cover the affected skin area with cream once per day. If excessive drying of the skin or rash occurs, reduce the application of cream or discontinue use. To speed relief, we recommend using Mite-B-Gone Sulfur-Lavender Soap. Some may be sensitive to sulfur or essential oils. Skin test for tolerability. If irritation or reaction occurs, discontinue use.

Inactive Ingredients: Aqua, Carbomer, Cetearyl Alcohol, Glyceryl Stearate, Helianthus Annus (Sunflower) Seed Oil, Phenoxyethanol, Polysorbate 20, Potassium Sorbate, Sodium Hydroxide, Tea Tree Oil

10% SULFUR

Topical Mite and Multi-Purpose Itch Cream

Questions? Comments? 866-371-2499

Mfd. by: Nature's Innovation, Inc.

5317 Palmero Ct., Buford, GA 30518

*These statements or claims are based upon traditional homeopathic practice. They have not been reviewed by the Food & Drug Administration. "X" is a homeopathic dilution.

Packaging

Package -60mL



NDC# 10893-430-02

Mite•B•Gone
10% SULFUR

Topical Mite and Multi-Purpose Itch Cream

2 oz. (60 mL)

| | | |
|-------------------|---|--|
| Drug Facts | Active Ingredients: Sulfur 1X-HPUS <i>The letters HPUS indicate the components in this product are homeopathic.</i> | Purpose: Mite Symptom Relief <i>The letters HPUS indicate the components in this product are homeopathic.</i> |
| | Uses: Symptomatic treatment of mite infestations. | |
| | Warnings: For external use only. Ask a doctor before use if pregnant or nursing. Avoid using near eyes, mouth or mucous membranes. If eye contact occurs, rinse thoroughly with water and consult a doctor. Keep out of reach of children. Do not use if tamper evident seal is broken. In case of ingestion call Poison Control Center hotline immediately at 1-800-222-1222. | |
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| | Inactive Ingredients: Aqua, Carbomer, Glycerol Alcohol, Glycerol Stearate, Helianthus Annuus (Sunflower) Seed Oil, Phenoxethanol, Polysorbate 20, Potassium Sorbate, Sodium Hydroxide, Tea Tree Oil | |

Questions? Comments? 1-866-371-2499
MIB, by Nature's Innovation, Inc.
5317 Palmero Ct., Buford, GA 30518

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Package - 118.3mL



NDC# 10893-430-04

Mite•B•Gone
10% SULFUR

Topical Mite and Multi-Purpose Itch Cream

4 oz. (118.3 mL)

| | | |
|-------------------|---|--|
| Drug Facts | Active Ingredients: Sulfur 1X-HPUS <i>The letters HPUS indicate the components in this product are homeopathic.</i> | Purpose: Mite Symptom Relief <i>The letters HPUS indicate the components in this product are homeopathic.</i> |
| | Uses: Symptomatic treatment of mite infestations. | |
| | Warnings: For external use only. Ask a doctor before use if pregnant or nursing. Avoid using near eyes, mouth or mucous membranes. If eye contact occurs, rinse thoroughly with water and consult a doctor. Keep out of reach of children. Do not use if tamper evident seal is broken. In case of ingestion call Poison Control Center hotline immediately at 1-800-222-1222. | |
| | Directions: Cleanse skin thoroughly before applying. Cover the affected skin area with cream once per day. If excessive drying of the skin or rash occurs, reduce the application of cream or discontinue use. To speed relief, we recommend using Mite-B-Gone Sulfur-Lavender Soap. Some may be sensitive to sulfur or essential oils. Skin test for tolerability. If irritation or reaction occurs, discontinue use. | |
| | Inactive Ingredients: Aqua, Carbomer, Glycerol Alcohol, Glycerol Stearate, Helianthus Annuus (Sunflower) Seed Oil, Phenoxethanol, Polysorbate 20, Potassium Sorbate, Sodium Hydroxide, Tea Tree Oil | |

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Package - 236.6mL



NDC# 10893-430-08

Mite•B•Gone
10% SULFUR

Topical Mite and Multi-Purpose Itch Cream

8 oz. (236.6 mL)

| | | |
|-------------------|---|--|
| Drug Facts | Active Ingredients: Sulfur 1X-HPUS <i>The letters HPUS indicate the components in this product are homeopathic.</i> | Purpose: Mite Symptom Relief <i>The letters HPUS indicate the components in this product are homeopathic.</i> |
| | Uses: Symptomatic treatment of mite infestations. | |
| | Warnings: For external use only. Ask a doctor before use if pregnant or nursing. Avoid using near eyes, mouth or mucous membranes. If eye contact occurs, rinse thoroughly with water and consult a doctor. Keep out of reach of children. Do not use if tamper evident seal is broken. In case of ingestion call Poison Control Center hotline immediately at 1-800-222-1222. | |
| | Directions: Cleanse skin thoroughly before applying. Cover the affected skin area with cream once per day. If excessive drying of the skin or rash occurs, reduce the application of cream or discontinue use. To speed relief, we recommend using Mite-B-Gone Sulfur-Lavender Soap. Some may be sensitive to sulfur or essential oils. Skin test for tolerability. If irritation or reaction occurs, discontinue use. | |
| | Inactive Ingredients: Aqua, Carbomer, Glycerol Alcohol, Glycerol Stearate, Helianthus Annuus (Sunflower) Seed Oil, Phenoxethanol, Polysorbate 20, Potassium Sorbate, Sodium Hydroxide, Tea Tree Oil | |

Questions? Comments? 1-866-371-2499
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5317 Palmero Ct., Buford, GA 30518

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DRUG FACTS LABEL

| Drug Facts | |
|---|---|
| Active Ingredients: Sulfur 1X HPUS | Purpose: Mite Symptom Relief <i>The letters HPUS indicate the component(s) in this product is (are) officially monographed in the Homeopathic Pharmacopeia of the United States.</i> |
| Uses: Symptomatic treatment of mite infections. | |
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NATURASIL MITE BE GONE

sulfur cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10893-430 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) | SULFUR | 0.1 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |

| | |
|---|--|
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| TEA TREE OIL (UNII: VIF565UC2G) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:10893-430-02 | 60 mL in 1 JAR; Type 0: Not a Combination Product | 09/11/2020 | |
| 2 | NDC:10893-430-04 | 118.3 mL in 1 JAR; Type 0: Not a Combination Product | 09/11/2020 | |
| 3 | NDC:10893-430-08 | 236.6 mL in 1 JAR; Type 0: Not a Combination Product | 09/11/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic | | 09/11/2020 | |

Labeler - Nature's Innovation, Inc (602969854)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| Nature's Innovation, Inc | | 602969854 | manufacture(10893-430) |

Revised: 10/2020

Nature's Innovation, Inc