GOUT CALM- antimonium crudum, berberis vulgaris, lithium carbonicum spray Silver Star Brands

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.

Healthful[™] Naturals GoutCalm - 59 ml

HPUS* Active ingredients

HPUS* Active ingredients - Equal volumes of each ingredient as follows: Antimonium crudum (6C), Berberis vulgaris (30C), Lithium carbonicum (6C).

*"HPUS" indicates the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.

Uses+:

Uses+: For symptomatic treatment of gout joint pain and inflammation.

+ As per various homeopathic materia medicas. These uses have not been evaluated by the FDA, and product has not been clinically tested.

Warnings

Warnings: If symptoms persist or worsen, discontinue use immediately and consult a healthcare professional.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children.

For external use only.

Avoid using near eyes or mouth.

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

Some individuals may be sensitive to essential oils. If irritation or reaction occurs, discontinue use.

Directions

Directions: Shake well before using.

Spray onto entire affected area and massage into skin every 2 hours until pain begins to subside.

Adults and children over 12 years of age.

Other information:

Intended to complement, not replace, standard medical care.

Tamper resistant for your protection. Use only if safety seal is intact.

Inactive ingredients

Inactive ingredients: Basil essential oil, black pepper essential oil, celery essential oil, grapeseed oil.

Keep out of reach of children.

If pregnant or breast-feeding, ask a health care professional before use.

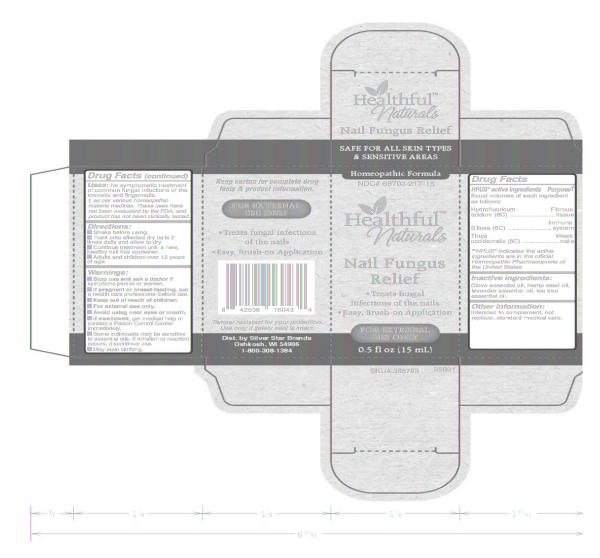
HPUS* Active ingredients Purpose+

Equal volumes of each ingredient as follows:

Antimonium crudum (6C).....Stiffness, swelling

Berberis vulgaris (30C).....Burning pain

Lithium carbonicum (6C).....Joint pain





GOUT CALM

Packaging

antimonium crudum, berberis vulgaris, lithium carbonicum spray

| Product Information | | | | | |
|-------------------------|----------------|--------------------|---------------|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68703-218 | | |
| Route of Administration | TOPICAL | | | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------|----------------------------|-----------------------|
| ANTIMONY TRISULFIDE (UNII: F79059A38U) (ANTIMONY TRISULFIDE - UNII:F79059A38U) | ANTIMONY TRISULFIDE | 6 [hp_C] in 59 mL |
| BERBERIS VULGARIS FRUIT (UNII: 6XEF22AHC3) (BERBERIS VULGARIS FRUIT - UNII:6XEF22AHC3) | BERBERIS VULGARIS FRUIT | 30 [hp_C] in 59 mL |
| LITHIUM CARBONATE (UNII: 2BMD2GNA4V) (LITHIUM CATION - UNII:8H8Z5UER66) | LITHIUM CARBONATE | 6 [hp_C] in 59 mL |

| Inactive Ingredients | | | | |
|-------------------------------------|----------|--|--|--|
| Ingredient Name | Strength | | | |
| BLACK PEPPER OIL (UNII: U17J84S19Z) | | | | |
| GRAPE SEED OIL (UNII: 930MLC8XGG) | | | | |
| BASIL OIL (UNII: Z129UMU8LE) | | | | |
| CELERY SEED OIL (UNII: 8MBL58728K) | | | | |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
|-----------------------|------------------------------------|-------------------------------------------------------------|-------------------------|-----------------------|--|
| | NDC:68703- 218-02 | 59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 01/14/2019 | | |
| | | | | | |
| Marketing Information | | | | | |
| Μ | larketing | Information | | | |
| M | larketing Marketing Category | Information Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| un | Marketing | Application Number or Monograph | - | - | |

Labeler - Silver Star Brands (006070379)

Registrant - Silver Star Brands (006070379)

| Establishment | | | | | |
|----------------|---------|-----------|----------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Vitality Works | | 137752817 | manufacture(68703-218) | | |

Revised: 3/2023

Silver Star Brands