**PRIVATE LABEL ANTIFUNGAL BARRIER CREAM- 2% miconazole nitrate cream cream**
**Swiss-American CDMO, LLC**

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**Antifungal Barrier Cream**

## Warnings

For external use only. Not intended for ingestion. Do not use on children under 2 years of age unless directed by a doctor. Avoid contact with the eyes. For the treatment of athlete's foot and ringworm: if irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor. For the treatment of jock itch: if irritation occurs or there is no improvement within 2 weeks discontinue use and consult a doctor. Do not use for diaper rash. Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away

## Use and Directions

Proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea sorporis). For the treatment of superficial skin infections caused by yeast (candida albicans). For effective relief of redness, irritation, scaling, itching, discomfort and burning.

Clean the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily as directed by a doctor or health care professional. For athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete's foot and ringworm, use daily for 4 weeks. For jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails.

## Keep out of reach of children

Keep out of reach of children

## Active Ingredient

Miconazole Nitrate 2.00%

## Inactive Ingredient

Allantoin, Beeswax, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Dimethicone, Disodium EDTA, Fragrance, Hydrogenated Castor Oil, Isopropyl Palmitate, Methylparaben, Petrolatum, Propylene Glycol, Propylparaben, Purified Water, Sodium Chloride, Zinc Oxide

## Labeling

**PRIVATE LABEL ANTIFUNGAL BARRIER CREAM**

2% miconazole nitrate cream cream

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:60232-0009 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **MICONAZOLE NITRATE** (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) | MICONAZOLE NITRATE | 20 g in 1000 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **WATER** (UNII: 059QF0KO0R) | |
| **ALLANTOIN** (UNII: 344S277G0Z) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PETROLATUM** (UNII: 4T6H12BN9U) | |
| **DIMETHICONE 1000** (UNII: MCU2324216) | |
| **CETYL DIMETHICONE 25** (UNII: U4AS1BW4ZB) | |
| **CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5)** (UNII: V2W71V8T0X) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **HYDROGENATED CASTOR OIL** (UNII: ZF94AP8MEY) | |
| **YELLOW WAX** (UNII: 2ZA36H0S2V) | |
| **ZINC OXIDE** (UNII: SOI2LOH54Z) | |
| **ISOPROPYL PALMITATE** (UNII: 8CRQ2TH63M) | |
| **CUCUMBER** (UNII: YY7C30VXJT) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:60232-0009-2 | 60 g in 1 TUBE; Type 0: Not a Combination Product | 11/22/2010 | |
| **2** | NDC:60232-0009-4 | 120 g in 1 TUBE; Type 0: Not a Combination Product | 11/22/2010 | |
| **3** | NDC:60232- | 150 g in 1 TUBE; Type 0: Not a Combination | 11/22/2010 | |

| | | | | |
|---|---|---|---|---|
| 3 | 0009-5 | Product | 11/22/2010 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M017 | 11/22/2010 | |

## Labeler - Swiss-American CDMO, LLC (080170933)

## Registrant - Swiss-American CDMO, LLC (080170933)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Swiss-American CDMO, LLC | | 080170933 | manufacture(60232-0009) |

Revised: 11/2023 Swiss-American CDMO, LLC