

ANTI-FUNGAL- miconazole nitrate cream
Universal Distribution Center LLC

Anti-Fungal Cream

Active Ingredient

Miconazole Nitrate 2.0%

Purpose

Antifungal

Uses

- cures most athlete's foot, jock itch, and ringworm.
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions.

Warnings

Do not use on children under 2 years of age except under the advice and supervision of a doctor.

For external use only.

When using this product avoid contact with eyes.

Stop using this product and ask a doctor

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch).
- do not use for diaper rash

Keep this and all drugs out of reach of children.

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

Directions

- wash affected area and dry thoroughly
- Apply a thin layer over affected area twice daily (morning and night) or as directed by a doctor
- supervise children in the use of this product
- 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 a day
- for athlete's foot and ringworm use daily for 4 weeks, for jock itch use daily for 2 weeks
- if conditions persist longer, ask a doctor
- this product is not effective on the scalp or nails.

Other information

- Store between 15°C to 30°C (59°F to 86°F)
- Lot No. & Exp. Date: see crimp of tube.

Inactive Ingredients

Benzoic Acid, Butylated Hydroxyanisole, Mineral Oil, PEGlicol-5-Oleate, Pegoxol-7 Stearate, Purified Water.

PRINCIPAL DISPLAY PANEL

Anti-Fungal Cream

NET WT 0.5 OZ (14 g)



ANTI-FUNGAL
miconazole nitrate cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52000-021 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|---------------|
| MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) | MICONAZOLE NITRATE | 0.02 g in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PEG-5 OLEATE (UNII: 0240V77G50) | |
| PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5) | |
| WATER (UNII: 059QF0KOOR) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:52000-021-41 | 1 in 1 BOX | 02/14/2022 | |
| 1 | NDC:52000-021-40 | 14 g in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M005 | 04/15/2015 | |

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Savvy Care And Cosmetics Pvt. Ltd. (915039748)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------|---------|-----------|------------------------|
| Savvy Care And Cosmetics Pvt. Ltd. | | 915039748 | manufacture(52000-021) |