

ANTIFUNGAL CREAM- 2% miconazole nitrate cream cream
Cardinal Health, 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.

Antifungal Cream

Warnings

- For external use only
- Avoid contact with eyes
- Keep out of reach of children
- If swallowed, get medical help or contact Poison Control Center right away
- For athlete's foot and ringworm, if irritation occurs or there is no improvement within 4 weeks, discontinue use and consult a physician
- For jock itch, if irritation occurs or there is no improvement within 2 weeks, discontinue use and consult a physician
- Do not use on deep or puncture wounds, animal bites, serious burns, for diaper rash, on children younger than 2 years of age.

Active Ingredients

Miconazole Nitrate 2% Antifungal

Uses

A clinically effective treatment for:

- most athlete's foot (tinea pedis)
- jock itch (tinea cruris)
- ringworm (tinea corporis)

Relieves itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch

Uses

A clinically effective treatment for:

most athlete's foot (tinea pedis)jock itch (tinea cruris)ringworm (tinea corporis)

Relieves itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch

Directions

- Gently cleanse the treatment area
- Pat dry
- Apply a thin layer of product to the affected area twice daily (morning and night) or as directed by a physician
- For athlete's foot, pay close attention to area between toes, wear well-fitting ventilated shoes, and change shoes and socks at least once daily
- Use daily for 4 weeks for treatment of athlete's foot and ringworm

- Use daily for 2 weeks for treatment of jock itch
- If condition persists longer, consult a physician
- This product is not effective on the scalp or nails

Directions

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Other Information

Store between 15-30°C (59-86°F)

Keep out of reach of children

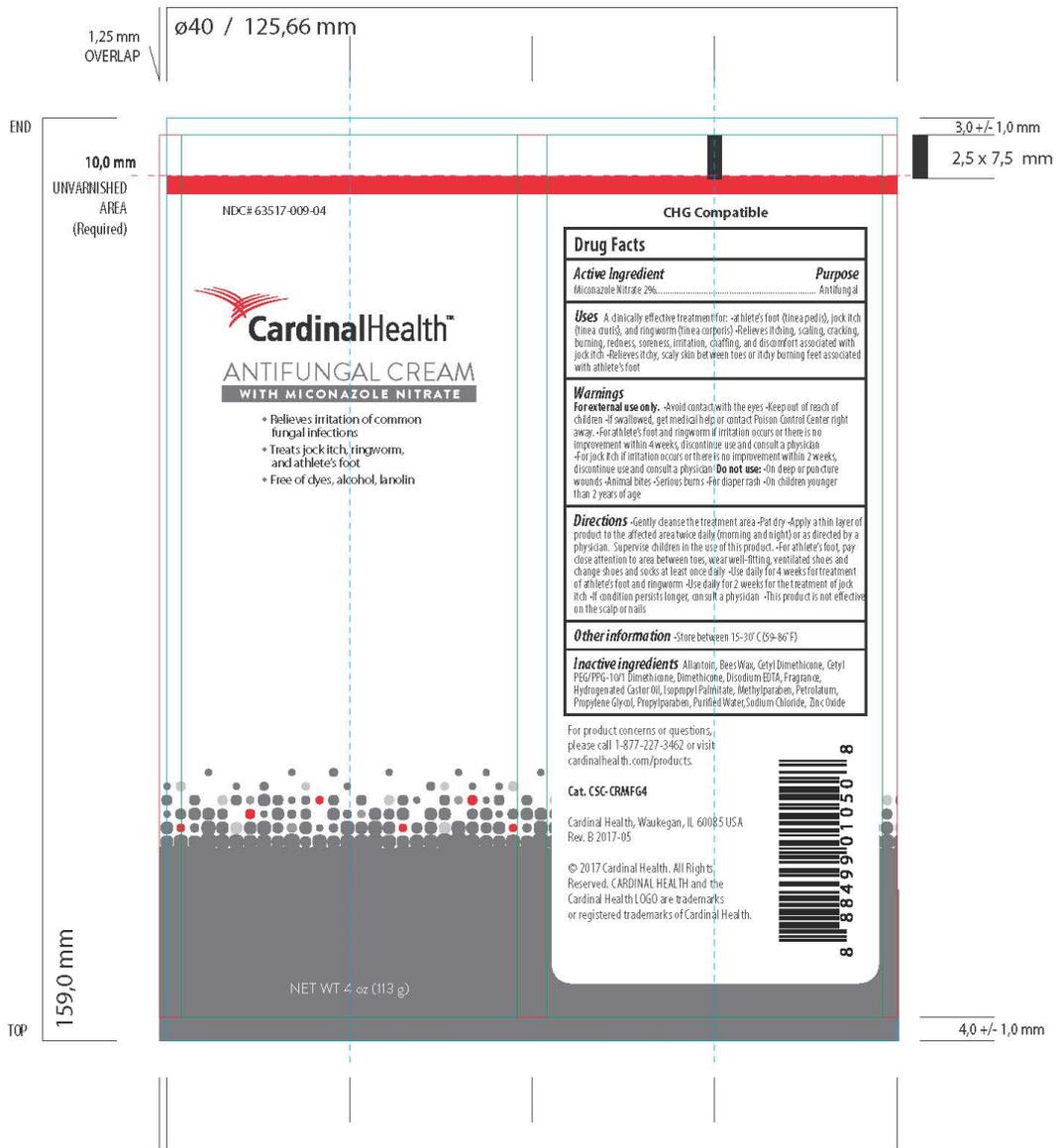
Keep out of reach of children

Inactive Ingredients

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

Die line ø40 x 159,0 mm



Art specifications: Each Tube - See Dieline
Do not alter art or size.
All art prints PMS 185C,
PMS Cool Gray 9 and 100% Black
 Project FY17_87 Rev. B 2017-05

- - - - Unvarnished area
- Die line
- Maximum print area
- Maximum art area for panel

LA CAZADORA, S.A. DE C.V.
 DATE: 27 APRIL 2016
 DIE: ø40 x 159,0 mm
 SALES CONTACT: PAULINA SANCHEZ
 ART CONTACT: LIC. ALEJANDRO MOLINA

ANTIFUNGAL CREAM

2% miconazole nitrate cream cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63517-009 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------|--------------|
| MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) | MICONAZOLE NITRATE | 2 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALLANTOIN (UNII: 344S277G0Z) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| DIMETHICONE 1000 (UNII: MCU2324216) | |
| CETYL DIMETHICONE 45 (UNII: IK315POC44) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |
| WHITE WAX (UNII: 7G1J5DA97F) | |
| HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY) | |
| ZINC OXIDE (UNII: SOI2LOH54Z) | |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) | |
| CUCUMBER FRUIT OIL (UNII: R81Y52NPCT) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63517-009-04 | 120 g in 1 TUBE; Type 0: Not a Combination Product | 01/01/2015 | |
| 2 | NDC:63517-009-05 | 5 g in 1 PACKET; Type 0: Not a Combination Product | 01/01/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333C | 01/01/2015 | |

Labeler - Cardinal Health, Inc. (961027315)

Revised: 11/2020

Cardinal Health, Inc.