

MICONAZOLE NITRATE- miconazole nitrate powder
AvKARE

Miconazole Nitrate 2%

Drug Facts

Active ingredient

Miconazole Nitrate 2.0%

Purpose

Antifungal

Uses

- for the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis)
- for the treatment of most superficial skin infections caused by yeast (candida albicans)
- relieves most itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch

Warnings

- **for external use only**

Do not use

- on children under 2 years of age unless by a doctor
- avoid contact with the eyes
- for athlete's foot and ringworm - if irritation occurs, or if there is no improvement within 4 weeks, discontinue use and consult a doctor
- for jock itch - if irritation occurs, or if there is no improvement within 2 weeks, discontinue use and consult a doctor

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean the affected area and dry thoroughly
- apply a thin layer of powder 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 toes; wear well - fitting, ventilated shoes, and change shoes and socks at least once daily
- for athletes 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

Other information

- protect from freezing. Avoid excessive heat.
- do not use if package is damaged

Inactive ingredients

allantoin, chloroxylenol, fragrance, imidazolidinyl urea, microcrystalline cellulose, tricalcium phosphate, corn starch

PRINCIPAL DISPLAY PANEL - 85 g Bottle Label

| MICONAZOLE NITRATE | | | |
|---------------------------------|--|--------------------|------------------------------|
| miconazole nitrate powder | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42291-938(NDC:69367-399) |
| 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 |

| | |
|--|--|
| ALLANTOIN (UNII: 344S277G0Z) | |
| CHLOROXYLENOL (UNII: 0F32U78V2Q) | |
| IMIDUREA (UNII: M629807ATL) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| TRICALCIUM PHOSPHATE (UNII: K4C08XP666) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|--|
| Color | white (White to off-white) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:42291-938-85 | 85 g in 1 BOTTLE; Type 0: Not a Combination Product | 06/05/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M005 | 06/05/2024 | |

Labeler - AvKARE (796560394)