

MICONAZOLE NITRATE- miconazole nitrate cream

A-S Medication Solutions

Miconazole Nitrate

Drug Facts

Active ingredient

Miconazole nitrate USP 2%

Purpose

Antifungal

Uses

- effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis)
- for effective relief of itching, scaling, burning and discomfort that can accompany these conditions.

Warnings

For external use only

Do not use on children less than 2 years of age unless directed by a doctor

When using this product avoid contact with eyes

Stop use and ask a doctor if

- irritation occurs
- condition persists
- there is no improvement of athlete's foot or ringworm within 4 weeks or jock itch within 2 weeks.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- clean the affected area and dry thoroughly
- apply a thin layer of the product 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 daily
- For athlete's foot and ringworm: use daily for 4 weeks.
- For jock itch: use daily for 2 weeks

- not effective on the scalp or nails

Other information

- To open: unscrew cap, use pointed end on cap to puncture seal
- store at 20° - 25°C (68° - 77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

apricot kernel oil, benzoic acid, BHT, glycol stearate, mineral oil, PEG-6, PEG-6-32 stearate, purified water

Questions?

Call **1-866-923-4914**

Distributed by:

Taro Pharmaceuticals

U.S.A., Inc.

Hawthorne, NY 10532

HOW SUPPLIED

Product: 50090-1071

NDC: 50090-1071-0 15 g in a TUBE / 1 in a CARTON

Miconazole Nitrate

NDC 50090-1071-0
 A-S Medication Solutions, LLC
 Product No. 5980-0
 LOT
**MICONAZOLE
 NITRATE 2%**
ANTIFUNGAL CREAM
 ACTIVE INGREDIENTS:
 MICONAZOLE NITRATE USP 2%
 PURPOSE: ANTIFUNGAL
 STORE AT 68 – 77 DEGREES F
 NET WT
 1/2 OZ (15G)



GTIN: 00350090107104
 LOT:
 EXP:
 S/N:

DISTRIBUTED BY:
 A – S Medication Solutions
 Libertyville, IL 60048

SOURCE NDC: 51672 – 2001 – 1

MICONAZOLE NITRATE

miconazole nitrate cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|--------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50090-1071(NDC:51672-2001) |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|--------------|
| MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) | MICONAZOLE NITRATE | 20 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| APRICOT SEED OIL (UNII: 54JB35T06A) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| GLYCOL STEARATE (UNII: 0324G66D0E) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PEG-6 (UNII: 5655G9Y8AQ) | |
| WATER (UNII: 059QF0KO0R) | |
| PEG-6 MONOSTEARATE (UNII: 8LQC57C6B0) | |
| PEG-32 MONOSTEARATE (UNII: 33GX5WQC0M) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50090-1071-0 | 1 in 1 CARTON | 11/28/2014 | |
| 1 | | 15 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 | 10/01/1991 | |

Labeler - A-S Medication Solutions (830016429)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---------------------|
| A-S Medication Solutions | | 830016429 | RELABEL(50090-1071) |

Revised: 2/2025

A-S Medication Solutions