

ALOE VESTA ANTIFUNGAL - miconazole nitrate ointment
ConvaTec, 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.

Drug Facts

Active Ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Uses

- Cures most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis).
- Relieves itching, scaling, cracking, burning, redness, soreness, irritation, and discomfort that accompany these conditions.
- For the treatment of most superficial skin infections caused by yeast (Candida albicans).
- Follow a physician's instructions when treating Candida.

Warnings

For external use only.

Do not use on

children under 2 years of age unless directed by a physician.

When using this product,

avoid contact with eyes.

If irritation occurs

or if there is no improvement within 2 weeks for jock itch, or 4 weeks for athlete's foot or ringworm, discontinue use and consult a physician.

Keep out of reach of children.

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

Directions

Clean the affected area and dry thoroughly.

- Apply a thin layer of ointment over affected area twice daily (morning and night) or as directed by a physician.
- Supervise children in use of this product.

For athlete's foot: Pay close 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 physician.
- This product is not effective on the scalp or nails.

Other Information

Store at 15°C - 30°C (59°F - 86°F).

Inactive Ingredients

Aloe Extract, Light Mineral Oil, Softisan 649, White Petrolatum.

PRINCIPAL DISPLAY PANEL

Drug Facts

| Active ingredient | Purpose |
|-----------------------|------------|
| Miconazole Nitrate 2% | Antifungal |

Uses • Cures most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis). • Relieves itching, scaling, cracking, burning, redness, soreness, irritation, and discomfort that accompany these conditions. • For the treatment of most superficial skin infections caused by yeast (*Candida albicans*). • Follow a physician's instructions when treating *Candida*.

Warnings For external use only.
Do not use on children under 2 years of age unless directed by a physician. When using this product, avoid contact with eyes. If irritation occurs or if there is no improvement within 2 weeks for jock itch, or 4 weeks for athlete's foot or ringworm, discontinue use and consult a physician. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Store at 15°C - 30°C (59°F - 86°F)

Manufactured for: **ConvaTec**
Skillman, NJ 08558
1-800-422-9811
Made in USA

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CSX0647A Case Order No. 325102

ALOE VESTA™

Antifungal Ointment

TREAT

Miconazole Nitrate 2%

CURES MOST:
Athlete's Foot
Ringworm
Jock Itch
Superficial Yeast Infections

NET WT. 2oz.(56g)

NDC 43553-3251-02

NDC 43553-3251-2

ConvaTec

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ALOE VESTA ANTIFUNGAL

miconazole nitrate ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43553-3251 |
| 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 |
|--------------------------------------|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |

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:43553-3251-2 | 56 g in 1 TUBE | | |
| 2 | NDC:43553-3251-5 | 141 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333C | 10/03/1997 | |

Labeler - ConvaTec, Inc. (947989757)

Registrant - ConvaTec, Inc. (947989757)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|---------------------|
| Guest Packaging LLC | | 001773076 | manufacture |

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------|---------|-----------|---------------------|
| Medicia | | 091396697 | manufacture |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|---------------------|
| ConvaTec, Inc. | | 947989757 | analysis |

Revised: 4/2011

ConvaTec, Inc.