

## **MICONAZOLE- miconazole cream**

**Kinray, 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.*

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### **Antifungal**

#### **Active Ingredient**

Miconazole Nitrate 2%

#### **Warnings**

##### **For External Use Only**

##### **Do not use**

- on children under 2 years of age unless directed by a doctor.
- for diaper rash

##### **When using this product**

- avoid contact with eyes

##### **Stop use and ask a doctor if**

- irritation occurs
- there is no improvement within 2 weeks when used for the treatment of jock itch
- there is no improvement within 4 weeks when used for athlete's foot or ringworm

#### **Uses**

- For treatment of 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 or itching burning feet

#### **Indications and Usage**

- Supervise children in the use of this product.

#### **Other information.**

Store at room temperature

#### **Directions**

- Clean the affected area and dry thoroughly. Apply a thin layer of cream 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 athlete's 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 scalp or nails.

## Inactive Ingredients

Inactive Ingredients: Cetomacrogol 1000, cetostearyl alcohol, chlorocresol, liquid paraffin, propylene glycol, purified water, white soft paraffin.

## Keep Out of Reach of Children

- **KEEP OUT OF REACH OF CHILDREN**
- If swallowed get medical help or contact a Poison Control Center right away

Principal Display Panel

Preferred Plus Pharmacy

Miconazole Nitrate Cream USP 2%

KR Miconazole.jpg

KIN # 943779

# Miconazole Nitrate

**CREAM USP, 2%      ANTIFUNGAL**

Compare to the active ingredient in Micatin®

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| <b>Drug Facts</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <i>Purpose</i> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <b>Active Ingredient</b><br>Miconazole Nitrate 2%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Antifungal     |
| <b>Uses</b><br>■ For the treatment of 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 or itching, burning feet                                                                                                                                                                                                                                                                                                                     |                |
| <b>Warnings</b><br>For external use only<br><b>Do not use</b><br>■ on children under 2 years of age unless directed by a doctor ■ for diaper rash<br><b>When using this product</b> ■ avoid contact with the eyes<br><b>Stop use and ask a doctor if</b><br>■ irritation occurs ■ there is no improvement within 2 weeks when used for the treatment of jock itch ■ there is no improvement within 4 weeks when used for athlete's foot or ringworm<br><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.                                |                |
| <b>Directions</b><br>■ Clean the affected area and dry thoroughly. Apply a thin layer of cream over affected area twice daily (morning and night) or as directed by a doctor. ■ Supervise children in the use of this product.<br>■ 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<br>■ 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. ▼ |                |

**Drug Facts (continued)**

**Other Information** ■ Store at room temperature

**Inactive Ingredients** Cetomacrogol 1000, Cetostearyl Alcohol, Chlorocresol, Liquid Paraffin, Propylene Glycol, Purified Water, White Soft Paraffin

All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.

Manufactured by: Dynarex Corp.  
Distributed by:  
**Kinray LLC Whitestone, NY 11357**  
For questions call our Toll Free number  
1-888-396-2739

6 167841 12917 4

Made in India

NET WT 28.4g (1 oz.)

# Miconazole Nitrate

## CREAM USP, 2%      ANTIFUNGAL

NDC # 61715-050-01

ANTIFUNGAL  
Miconazole Nitrate  
CREAM USP, 2%

Relieves Itching & Burning  
Greaseless & Nonstaining  
Cures Athlete's Foot

Compare to the active  
ingredient in Micatin®

KIN # 943779



## MICONAZOLE

miconazole cream

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:61715-050 |
| 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 |
|----------------------------------------|----------|
| CETETH-20 (UNII: I835H2IHHX)           |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) |          |
| CHLORO CRESOL (UNII: 36W53O7109)       |          |
| LIGHT MINERAL OIL (UNII: N6K5787QVP)   |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)    |          |
| WATER (UNII: 059QF0KO0R)               |          |
| MINERAL OIL (UNII: T5L8T28FGP)         |          |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

|   |                  |                                                     |            |  |
|---|------------------|-----------------------------------------------------|------------|--|
| 1 | NDC:61715-050-01 | 28.4 g in 1 TUBE; Type 0: Not a Combination Product | 03/22/2013 |  |
|---|------------------|-----------------------------------------------------|------------|--|

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | part333C                                 | 03/21/2013           |                    |

**Labeler** - Kinray, Inc. (012574513)

**Registrant** - Dynarex Corporation (008124539)

Revised: 6/2017

Kinray, Inc.