# TOLNAFTATE- tolnaftate cream Discount Drug Mart, 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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### Discount Drug Mart Tolnaftate Antifungal Cream

### **Active Ingredients**

Tolnaftate 1%

### Purpose

Antifungal

#### Uses

- clinically proven to cure most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevnet most athlete's foot from recurring when used daily
- effectively soothes and relieves symptoms of athlete's foot, including itching, burning and cracking

### Warnings

For external use only

### When using this product

avoid contact with the eyes

### Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

#### Do not use

on children under 2 years of age except under the advice and supervision of a doctor

### Keep out of reach of children

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

#### Directions

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- 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
- use daily for 4 weeks; if condition persists longer, ask a doctor
- to prevent athlete's foot, apply once or twice daily (morning and/or night)
- this product is not effective on the scalp or nails

#### Other Information

• store between 2° and 30°C (36° and 86°F)

### **Inactive ingredients**

Carbomer, Cetyl alcohol, Chlorocresol, Dibasic sodium phosphate hydrate, Glycerin, Glyceryl monostearate, Light liquid paraffin, Myristoyl/palmitoyl oxostearamide/arachamide MEA, PEG-15 glyceryl stearate, Stearic acid, Water

### **Principal Display Panel**

Tolnaftate



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Drug Facts(continued)

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legnu†ijnA. Purpose

Tolnaftate 1%.. Active ingredients (in each gram)

Drug Facts



### **TOLNAFTATE**

tolnaftate cream

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:53943-994 |
| Route of Administration | TOPICAL        |                    |               |

| Active Ingredient/Active Moiety                              |                   |              |  |
|--|-------------------|--------------|--|
| Ingredient Name  | Basis of Strength | Strength     |  |
| TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV) | TOLNAFTATE        | 1 g in 100 g |  |

| Inactive Ingredients   |          |  |
|--|----------|--|
| Ingredient Name  | Strength |  |
| CETYL ALCOHOL (UNII: 936JST6JCN)   |          |  |
| GLYCERIN (UNII: PDC6A3C0OX)  |          |  |
| GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)                              |          |  |
| PARAFFIN (UNII: 19 O0 E3H2ZE)  |          |  |
| STEARIC ACID (UNII: 4ELV7Z65AP)  |          |  |
| WATER (UNII: 059QF0KO0R)   |          |  |
| CHLORO CRESOL (UNII: 36 W53O7109)  |          |  |
| SODIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)                            |          |  |
| MYRISTO YL/PALMITO YL O XO STEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8 G7) |          |  |

| Packaging          |   |                             |                           |
|--------------------|---|-----------------------------|---------------------------|
| # Item Code        | Package Description                                 | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1 NDC:53943-994-01 | 1 in 1 BOX  | 11/09/2015                  |                           |
| 1                  | 28.3 g in 1 TUBE; Type 0: Not a Combination Product |                             |                           |

| I | <b>Marketing Infor</b> | mation                                   |                      |                    |
|---|------------------------|--|----------------------|--------------------|
| I | Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |

| OTC monograph final | part333C | 11/09/2015 |
|---------------------|----------|------------|
|                     |          |            |

## Labeler - Discount Drug Mart, Inc. (047741335)

Revised: 12/2020 Discount Drug Mart, Inc.