

**FAMILY CARE ANTIFUNGAL- tolnaftate cream
United Exchange Corp.**

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.

Family Care Tolnaftate Cream 1 oz 502

Active ingredient Purpose

Tolnaftate 1%.....Antifungal

Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevent most athlete's foot with daily use
- for effective relief of 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 immediately.

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; 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 20° to 25°C (68° to 77°F)
- Lot No. & Exp. Date: see box or see crimp of tube

Inactive ingredients

cetostearyl alcohol, ethylparaben, glycerin, light mineral oil, propylene glycol, purified water, sodium sulfite, stearth-20, stearic acid

Distributed by:

United Exchange Corp.

5836 Corporate Ave.

Cypress, CA 90630 USA

1-800-814-8028

Made in China

FAMILY CARE™

- Cures and Prevents Most Athlete's Foot
- Relieves Itching & Burning
- Fights Fungal Infections

TOLNAFTATE 1%
ANTIFUNGAL CREAM

TOLNAFTATE 1%
ANTIFUNGAL CREAM

Compare to the active ingredient in **Tough Actin®** Tinactin® Antifungal Cream*



- Cures and Prevents Most Athlete's Foot
- Relieves Itching & Burning
- Fights Fungal Infections

ORIGINAL STRENGTH

TOLNAFTATE 1%
ANTIFUNGAL CREAM

NET WT 1 OZ (28 g)

FAMILY CARE™



Distributed By: UNITED EXCHANGE CORP.
Cypress, CA 90630 USA | 1-888-645-8204
502-ZDP-BX-R3 | OM-MD-ZDP100-R2
Made In China

LOT & EXP.

Drug Facts (continued)

Active ingredient: Tolnaftate 1% Antifungal

Purpose: Antifungal

Uses: Tolnaftate 1% is effective in the treatment of most athlete's foot (thru heels and toenails) and ringworm (ringworm on feet).

Warnings: Do not use on children under 2 years of age except under the advice and supervision of a doctor. 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. ■ Wash affected area and dry thoroughly (morning and night) or as directed by a doctor. ■ Apply a thin layer of the product over affected area twice daily. ■ Surprised children in the use of this product.

Directions: ■ Wash affected area and dry thoroughly (morning and night) or as directed by a doctor. ■ Apply a thin layer of the product over affected area twice daily.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Use immediately. ■ If pregnant or breast-feeding, ask a health professional before use.

Other information: ■ This product is not effective on the scalp or nails. ■ Store at room temperature 20-25°C (68-77°F).

Inactive ingredients: castorbean alcohol, ethylparaben, glycerin, propylene glycol, petroleum, propylene glycol, purified water, sodium sulfite, stearyl-20, stearic acid.

Questions or comments? Call 1-888-645-8204.

This product is not manufactured or distributed by Bayer Health Care LLC, distributor of Tough Actin® Tinactin® Antifungal Cream.

KEEP OUT OF REACH OF CHILDREN.
KEEP THIS AND ALL OTHER MEDICINE OUT OF REACH OF CHILDREN.
DO NOT USE IF TAMPERS EVIDENT. DO NOT USE IF CAPTION IS OPEN OR PILL UNDER CAP.
IS BROKEN OR MISSING.

FAMILY CARE™

FAMILY CARE ANTIFUNGAL

tolnaftate cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:65923-021 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV) | TOLNAFTATE | 10 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM SULFITE (UNII: VTK01UQK3G) | |
| STEARETH-20 (UNII: L0Q8IK9E08) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| ETHYLPARABEN (UNII: 14255EXE39) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:65923-021-28 | 1 in 1 CARTON | 01/02/2017 | |
| 1 | | 28 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 final | part333C | 01/02/2017 | |

Labeler - United Exchange Corp. (840130579)