KROGER ANTIFUNGAL- terbinafine hydrochloride cream Kroger Company

Kroger_® Antifungal

Drug Facts

Active ingredient

Terbinafine hydrochloride 1%

Purpose

Antifungal

Uses

- cures most athlete's foot (tinea pedis)
- cures most jock itch (tinea cruris) and ringworm (tinea corporis)
- relieves itching, burning, cracking and scaling which accompany these conditions

Warnings

For external use only

Do not use

- on nails or scalp
- in or near the mouth or eyes
- for vaginal yeast infections

When using this product do not get into eyes. If eye contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if

• too much irritation occurs or gets worse

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and over:
 - use the tip of the cap to break the seal and open the tube
 - wash the affected skin with soap and water and dry completely before applying
 - **for athlete's foot** wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.
 - **between the toes only:** apply twice a day (morning and night) for **1 week** or as directed by a doctor
 - **on the bottom or sides of the foot:** apply twice a day (morning and night) for **2 weeks** or as directed by a doctor
 - **for jock itch and ringworm:** apply once a day (morning **or** night) for **1 week** or as directed by a doctor
 - wash hands after each use

• children under 12 years: ask a doctor



1 week between the toes



2 weeks on the bottom or sides of the foot

Other information

TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE.

- store at controlled room temperature 20° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol

Questions?

call **1-800-632-6900**

DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

Kroger®

Athlete's Foot Cream Terbinafine Hydrochloride Cream 1%

ANTIFUNGAL

Clinically Proven to Cure Most Athlete's Foot Between the Toes

Relieves Itching

NET WT 0.5 OZ (15 g)

NDC 30142-080-01



FULL PRESCRIPTION STRENGTH

Athlete's **Foot Cream**

Terbinafine Hydrochloride Cream 1% ANTIFUNGAL

*All trademarks are property

of their respective owners,

This product is not affiliated with the

makers/owners of

Lamisil AT®.

Clinically Proven to Cure Most **Athlete's Foot Between the Toes**

Relieves Itching

CINCINNATI, OHIO 45202

DISTRIBUTED BY

THE KROGER CO.

MADE IN CANADA

800-632-6900 www.kroger.com

QUALITY GUARANTEE

NET WT 0.5 OZ (15 g)

NO VARNISH/ NO AQ NO COPY / NO COLOR THIS FLAP FOR LOT # AND EXP DATE PRINT

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Drug Facts (continued)

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Drug Facts (continued)

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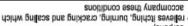
ON THIS FLAP NO VARNISH



B118.2 ENG19.68

NO VARNISH



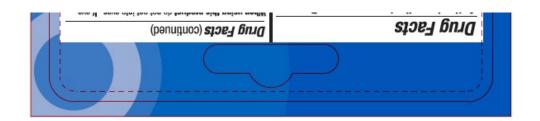


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Active ingredient

legnuttrnA. Purpose



KROGER ANTIFUNGAL

terbinafine hydrochloride cream

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| 1 | | | |
|--|-------------------|--------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| Terbinafine Hydrochloride (UNII: 012C11ZU6G) (Terbinafine - UNII:G7RIW8S0XP) | Terbinafine | 1 g in 100 g | |

Inactive Ingredients Ingredient Name Strength benzyl alcohol (UNII: LKG8494WBH) cetyl alcohol (UNII: 936JST6JCN) cetyl palmitate (UNII: 5ZA2S6B08X) isopropyl myristate (UNII: 0RE8K4LNJS) polysorbate 60 (UNII: CAL22UVI4M) water (UNII: 059QF0KO0R) sodium hydroxide (UNII: 55X04QC32I) sorbitan monostearate (UNII: NVZ4I0H58X) stearyl alcohol (UNII: 2KR8914H1Y)

| Product Characteristics | | | |
|-------------------------|-------|--------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

|] | Packaging | | | |
|---|------------------|---|----------------------|--------------------|
| # | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:30142-080-01 | 1 in 1 CARTON | 07/02/2007 | |
| 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 |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA077511 | 07/02/2007 | |
| | | | |

Labeler - Kroger Company (006999528)

Registrant - Taro Pharmaceuticals U.S. A., Inc. (145186370)

| Establishment | | | | |
|---------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Taro Pharmaceuticals Inc. | | 206263295 | MANUFACTURE(30142-080) | |

Revised: 7/2020 Kroger Company