KROGER ANTIFUNGAL- terbinafine hydrochloride cream Kroger Company

 $Kroger_{\mathbb{R}}$ 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 the eyes
- for vaginal yeast infections

When using this product do not get into the 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 older
 - 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



Other information

- do not use if seal on tube is broken or is not visible
- store at controlled room temperature 20°-25°C (68°-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 or comments?

1-800-632-6900

DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

Kroger_® FROM OUR FAMILY TO YOURS

athlete's foot cream TERBINAFINE HYDROCHLORIDE CREAM 1% ANTIFUNGAL CREAM

NET WT 0.5 OZ (15 g)



COMPARE TO the active ingredient in LAMISIL AT® *See back panel



athlete's foot cream

TERBINAFINE HYDROCHLORIDE CREAM 1%

ANTIFUNGAL CREAM

- Cures Most Athlete's Foot
- Relieves Itching & Burning
- Full Prescription Strength



LPK-6083-0513-1 M173



TERBINAFINE HYDROCHLORIDE CREAM 1%

ANTIFUNGAL CREAM

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Drug Facts (continued)





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QUALITY GUARANTEE www.kroger.com MADE IN CANADA.



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KROGER ANTIFUNGAL

terbinafine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:30142-080
Route of Administration	TOPICAL	DEA Schedule	

ı	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
ı	Terbinafine Hydrochloride (Terbinafine)	Terbinafine	1 g in 100 g	

Inactive Ingredients				
Ingredient Name	Strength			
benzyl alcohol				
cetyl alcohol				
cetyl palmitate				
isopropyl myristate				
polysorbate 60				
water				
sodium hydroxide				
sorbitan monostearate				
stearyl alcohol				

Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-080-01	1 in 1 CARTON		
1		15 g in 1 TUBE		

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: 6/2013 Kroger Company