# KROGER ANTIFUNGAL- terbinafine hydrochloride cream Kroger Company

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#### Kroger<sub>®</sub> 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%

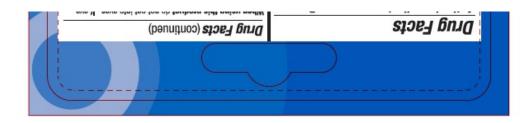
ANTIFUNGAL

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

**Relieves Itching** 

NET WT 0.5 OZ (15 g)





<b>KROGER AN</b> ' terbinafine hydrochlo		AL							
Product Informat	ion								
Product Type		HUMAN OTC DRUG Item Code (Source		Code (Source)	) NDC:30142-080		2-080		
Route of Administrat	tion	TOPICAL							
Active Ingredient	/Active Mo	iety							
	Ir	ıgredient Name			Basis of S	Strength	Strength		
Terbinafine Hydrochlo	oride (UNII: 01)	- C11ZU6G) (Terbinafine - UNII:G7RIW8S0XP)			Terbinafine 1 g in 2		1 g in 100 g		
Inactive Ingredients									
Ingredient Name							Strength		
benzyl alcohol (UNII: LKG8494WBH)									
cetyl alcohol (UNII: 936JST6JCN)									
cetyl palmitate (UNII: 5									
isopropyl myristate (U		JJS)							
polysorbate 60 (UNII: 0									
water (UNII: 059QF0KC		n							
sodium hydroxide (UN									
sorbitan monostearate		(H38 X)							
stearyl alcohol (UNII: 2KR8914H1Y)									
<b>Product Characte</b>	ristics								
Color		WHITE	TE Score						
Shape			Size						
Flavor			Imprint Co	mprint Code					
Contains									
Packaging									
# Item Code	Package Description			Marketing S	Start Date	Marketin	g End Date		
<b>1</b> NDC:30142-080-01	1 in 1 CARTON			07/02/2007			-		
1	15 g in 1 TUBE	g in 1 TUBE; Type 0: Not a Combination Product							
Marketing Info	ormation								

Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA077511	07/02/2007	

## Labeler - Kroger Company (006999528)

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

### Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(30142-080)

Revised: 7/2020

Kroger Company