#### ATHLETES FOOT- terbinafine hydrochloride cream Chain Drug Marketing Association, Inc.

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#### Athlete's Foot Cream

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.
- side effects occur.

**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.

2 weeks on the bottom or sides of the foot



- **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.

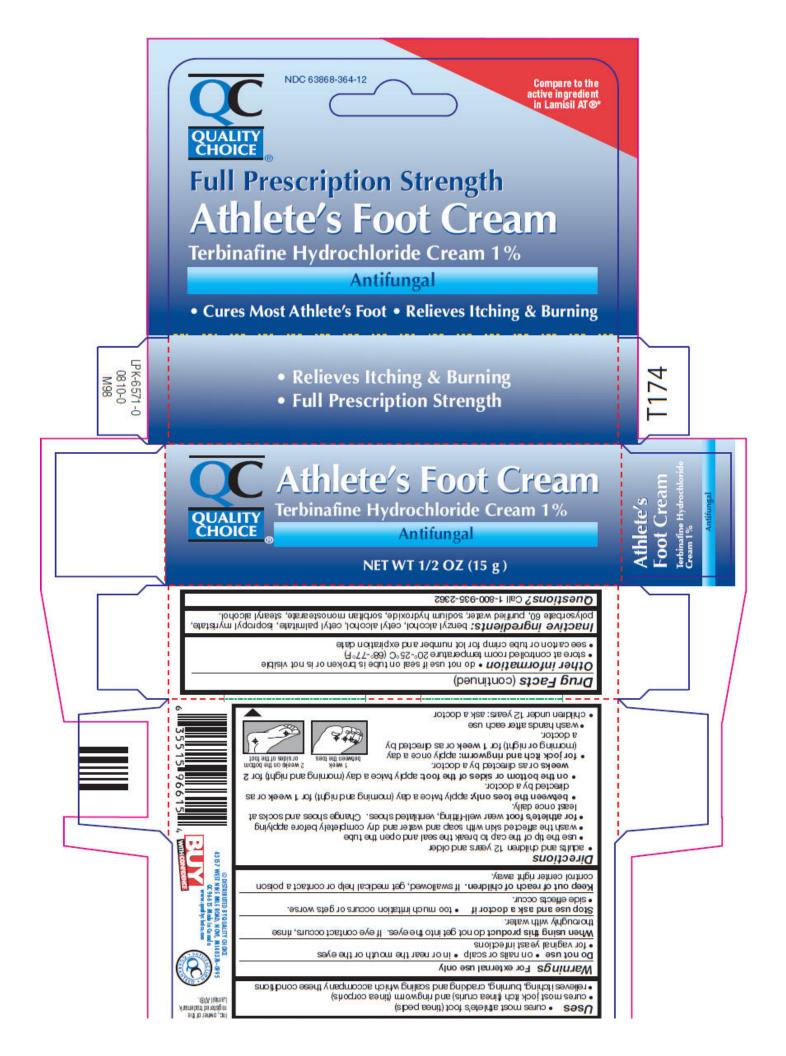
#### Questions?

Call 1-800-935-2362

DISTRIBUTED BY QUALITY CHOICE 43157 WEST NINE MILE ROAD, NOVI, MI 48376-0995

**PRINCIPAL DISPLAY PANEL - 15 g Tube Carton** 

QC QUALITY CHOICE® Athlete's Foot Cream Terbinafine Hydrochloride Cream 1% Antifungal NET WT 1/2 OZ (15 g )



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ATHLETES FOOT	-						
terbinafine hydrochloride	cream						
<b>Product Information</b>							
Product T ype		HUMAN OTC DRUG	Ite m Code	e (Sour	ce)	NDC:63868	3-364
Route of Administration		TOPICAL					
Active Ingredient/Acti	ive Moie	ty					
		edient Name			Basis of S	Strength	Strength
Terbinafine Hydrochloride	-		UNII:G7RIW8S0XP)	)	Terbinafine Hy	_	1 g in 100 g
Inactive Ingredients							
		Ingredient Name				Str	ength
benzyl alcohol (UNII: LKG84	494WBH)						
cetyl alcohol (UNII: 936JST6JCN)							
cetyl palmitate (UNII: 5ZA2S	56B08X)						
isopropyl myristate (UNII: 0	RE8K4LNJ	S)					
polysorbate 60 (UNII: CAL22	2UVI4M)						
water (UNII: 059QF0KO0R)							
sodium hydroxide (UNII: 552							
sorbitan monostearate (UN		158X)					
stearyl alcohol (UNII: 2KR89	914HLY)						
Product Characteristi	cs						
Color		VHITE	Score				
Shape			Size				
Flavor			Imprint Code				
Contains			-				
Packaging							
# Item Code	Pack	age Description	Marketing S	Start D	ate	Marketing 1	End Date
1 NDC:63868-364-12	1 in 1 CAR	TON					
1	15 g in 1 T	UBE					
<b>Marketing Inform</b>	ation						

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077511	07/02/2007	

# Labeler - Chain Drug Marketing Association, Inc. (011920774)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(63868-364)

Revised: 12/2012

Chain Drug Marketing Association, Inc.