# ATHLETES FOOT- terbinafine hydrochloride cream Topco Associates LLC

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#### **Athletes 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 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 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

2 weeks on the bottom

• children under 12 years: ask a doctor

1 week or sides between of the the toes foot





# Other information

- do not use if seal on tube is broken or is 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 **1-888-423-0139** 

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007

# PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

 $TopCare_{\mathbb{R}}$  health $_{TM}$ 

FULL PRESCRIPTION STRENGTH

Athlete's Foot Cream

TERBINAFINE HYDROCHLORIDE CREAM 1% • ANTIFUNGAL

• OUR PHARMACISTS RECOMMEND •

NET WT 0.5 OZ (15 g)

NDC 36800-080-01

COMPARE TO LAMISIL AT® **ACTIVE INGRED ENT\*** 

# **Athlete's Foot Cream**

TERRINAFINE HYDROCHLORID FCREAM 1% • ANTIFLINGAL

Cures Most Athlete's Foot

#### **RELIEVES:**

- Itching Burning
- Cracking
   Scaling

LPK-6045-3 1218-3 14

NO COPY ON THIS FLAP FOR LOT# AND EXPIRY

**+**TopCare ® health ™

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Athlete's Foot Cream

TERBINAFINE HYDROCHLORIDE CREAM 1% • ANTIFUNGAL

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"This product is not manufactured or distributed by Novartis Consumer He alth, Inc., owner of the registered trade mark Lamissi AT®.
DISTRIBUTED BYTO PCO ASSOCIATES LLC
ELKGROVE VILLAGE, IL 60007
© TOPCO TARAOS18

QUESTIONS?1-888-423-0139

Visit here for more information: http://topbrnds.com/48zr51



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ON THIS FLAP

This TopCare® productis aboratory

You rtotal satisfaction is guaranteed.

tested to guarantee its highes tquality.

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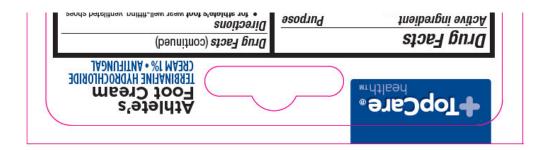
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Terbinafine hydrochloride 1%..

ON THIS FLAP NO VARNISH



# ATHLETES FOOT

terbinafine hydrochloride cream

<b>Product Info</b>	rmation
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:36800-080
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Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength

**Terbinafine Hydrochloride** (UNII: 012C11ZU6G) (Terbinafine - UNII:G7RIW8S0XP)

Terbinafine Hydrochloride 1 g in 100 g

# **Inactive Ingredients**

3				
Ingredient Name	Strength			
benzyl alcohol (UNII: LKG8494WBH)				
cetyl alcohol (UNII: 936JST6JCN)				
cetyl palmitate (UNII: 5ZA2S6B08X)				
isopropyl myristate (UNII: 0 RE8 K4LNJS)				
polysorbate 60 (UNII: CAL22UVI4M)				
water (UNII: 059QF0KO0R)				
sodium hydroxide (UNII: 55X04QC32I)				
sorbitan monostearate (UNII: NVZ4I0 H58 X)				
stearyl alcohol (UNII: 2KR8914H1Y)				

#### **Product Characteristics**

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

#### **Packaging**

#	# Item Code Package Description		<b>Marketing Start Date</b>	Marketing End Date
1	NDC:36800-080-01	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 - Topco Associates LLC (006935977)

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(36800-080)	

Revised: 3/2019 Topco Associates LLC