

TERBINAFINE HYDROCHLORIDE - terbinafine hydrochloride cream

Physicians Total Care, Inc.

Terbinafine Hydrochloride

Cream 1%

Antifungal 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 ring worm (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. You may report side effects to FDA at 1-800-FDA-1088.

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

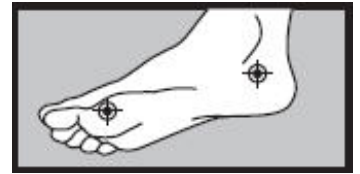
1 week between the toes



2 weeks on the bottom or sides of the foot

on the bottom of soles of the feet apply three 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.

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

Additional barcode labeling by:

Physicians Total Care, Inc.

Tulsa, Oklahoma 74146

PRINCIPAL DISPLAY PANEL - 30 g Carton

Cures Most Athlete's Foot

Compare to the
active ingredient
in Lamisil AT®*

Cures Most Athlete's Foot

Terbinafine Hydrochloride Cream 1% Antifungal Cream



- Relieves Itching & Burning
- Full Prescription Strength

LPK-6119-0
0408-0
M116

T1175

Cures Most Athlete's Foot

Full Prescription Strength

Terbinafine Hydrochloride Cream 1% Antifungal Cream

NET WT 1 oz (30 g)

Terbinafine
Hydrochloride
Cream 1%
Antifungal Cream



Drug Facts (continued)

Other information

- see carton or tube crimp for lot number and expiration date
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- do not use if seal on tube is broken or is not visible
- Inactive ingredients:** benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol.

Made in Canada
TAFD is a registered
Pharmaceutical U.S.A., Inc.
Hawthorne, NY 10532
U.S.A., Inc.
Taro Pharmaceuticals
Distributed by:



This product is
not manufactured
or distributed by
Novartis Consumer
Health, Inc., owner
of the registered
trademark
Lamisil AT®.

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Directions

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- 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 1 week
- 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

Illustrations:

- 1 week between the toes
- 2 weeks on the bottom or sides of the foot

Full Prescription Strength

NET WT 1 oz (30 g)



TERBINAFINE HYDROCHLORIDE

terbinafine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-5992(NDC:51672-2080)
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

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: 2KR89I4H1Y)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-5992-0	1 in 1 CARTON		
1		30 g in 1 TUBE		
2	NDC:54868-5992-1	1 in 1 CARTON		
2		15 g in 1 TUBE		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA077511	02/24/2009	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment			
Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel(54868-5992)

Revised: 2/2014

Physicians Total Care, Inc.