

ANTIFUNGAL FOOT- terbinafine hydrochloride cream
American Sales Company

Antifungal 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 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.

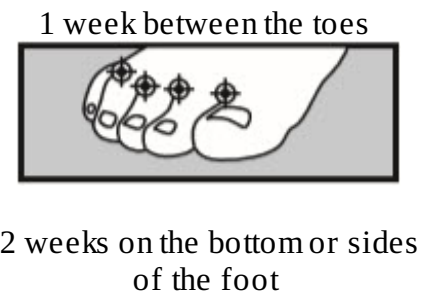
Stop use and ask a doctor if

- too much irritation occurs or gets worse.

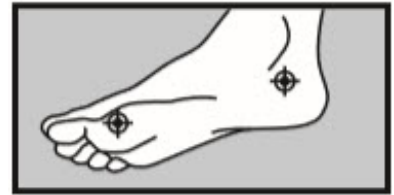
Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

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



- **ON THE BOTTOM OF 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?

Call **1-866-923-4914**

DISTRIBUTED
BY: FOODHOLD
U.S.A., LLC
LANDOVER, MD
20785

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

NDC 41520-080-02

Compare to the
active ingredient
in Lamisil AT®*

CAREone®

Antifungal Cream
Terbinafine Hydrochloride Cream 1% • Antifungal

Full Prescription Strength

OUR PHARMACISTS
RECOMMEND
Rx

NET WT 1 OZ (30 g)

Cures Most Athlete's Foot •
Relieves Itching & Burning •

NDC 41520-080-02

CAREone®

Compare to the active ingredient in Lamisil AT**

Antifungal Cream

Terbinafine Hydrochloride Cream 1% • Antifungal

CAREone®

Antifungal Cream

Terbinafine Hydrochloride Cream 1% • Antifungal

LPK-0043-3
0319-3
35

T175

Full Prescription Strength



Terbinafine Hydrochloride

Cream 1% • Antifungal

NET WT 1 OZ (30 g)

Cures Most Athlete's Foot •
Relieves Itching & Burning •



8111

\$3.95

Drug Facts (continued)

Other information • do not use if seal or tube is broken or is no tube
 • 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, dimethyl myristate, polyacrylate 60, purified water, sorbitan monooleate, stearyl alcohol

Keep this and all other medicines out of the reach of children. See the back of this package for more information.

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 BY: FOOOH OLD
 U.S.A., LLC
 LANCOVER, MD
 20785
 PR OCU CT OF
 CAWA,DA
 1-877-846-9349
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 D elhaize
 Le ening Sant
 Quality
 guaranteed or
 your money
 back



2 weeks on the bottom or sides of the foot



1 week between the toes

Directions

• 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
 • 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 lock itch and ingrown toenails: apply once a day (morning or night) for 1 week or as directed by a doctor
 • wash hands after each use
 • child ren under 12 years: ask a doctor

Warnings

For external use only

Do not use • on nails or scalp • in or near the mouth or the eyes • in 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.

Uses

• cures most athlete's foot (tinea pedis)
 • cures most lock itch (tinea corporis) and ringworm (tinea capitis)
 • relieves itching, burning, cracking and scaling which accompany these conditions

Drug Facts

Active ingredient
 Terbinafine hydrochloride 1%
Purpose
 Antifungal

ANTIFUNGAL FOOT

terbinafine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-080
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: 059QF0K00R)	
sodium hydroxide (UNII: 55X04QC32I)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
stearyl alcohol (UNII: 2KR89I4HIY)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-080-02	1 in 1 CARTON	07/02/2007	
1		30 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 - American Sales Company (809183973)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(41520-080)

Revised: 4/2019

American Sales Company