TERBINAFINE HYDROCHLORIDE- terbinafine hydrochloride cream
Taro Pharmaceuticals U.S.A., 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 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.

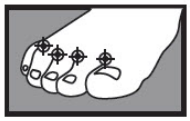
Stop use and ask a doctor if too much irritation occurs or gets worse

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

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 **1-866-923-4914**

Distributed by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

NDC 51672-2080-2
Full Prescription Strength

FOR ATHLETE'S FOOT

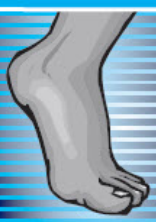
Terbinafine Hydrochloride
Cream 1%
Antifungal

NET WT 1 oz (30 g)

CLINICALLY PROVEN TO CURE
MOST ATHLETE'S FOOT BETWEEN THE TOES

Terbinafine Hydrochloride
Cream 1%
Antifungal

Compare to the active ingredient in Lamisil AT®*



- *Relieves Itching*
- *Full Prescription Strength*

LPK-6119-1
0220-1
76

T175
B76.2
ENG19.54

NDC 51672-2080-2

FOR ATHLETE'S FOOT

Terbinafine Hydrochloride
Cream 1%
Antifungal

Full Prescription Strength

NET WT 1 oz (30 g)

Terbinafine Hydrochloride
Cream 1%
Antifungal

* All trademarks are property of their respective owners.

Distributed by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532

TARO is a registered trademark of
Taro Pharmaceuticals U.S.A., Inc.
Made in Canada

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NO VARNISH ON THIS FLAP

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TERBINAFINE HYDROCHLORIDE

terbinafine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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:51672-2080-1	1 in 1 CARTON	07/02/2007	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-2080-2	1 in 1 CARTON	07/02/2007	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:51672-2080-8	1 in 1 CARTON	07/02/2007	
3		12 g in 1 TUBE; Type 0: Not a Combination Product		

4	NDC:51672-2080-9	1 in 1 CARTON	07/02/2007	
4		24 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:51672-2080-6	1 in 1 CARTON	07/02/2007	
5		45 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:51672-2080-3	1 in 1 CARTON	07/02/2007	
6		60 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:51672-2080-4	1 in 1 CARTON	04/24/2017	
7		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 - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2080)

Revised: 3/2020 Taro Pharmaceuticals U.S.A., Inc.