

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

Terbinafine Hydrochloride

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.

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
- 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° 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 - 15 g Tube Carton

Cures Most Ringworm
Full Prescription Strength

Terbinafine Hydrochloride
Cream 1%

Antifungal Cream

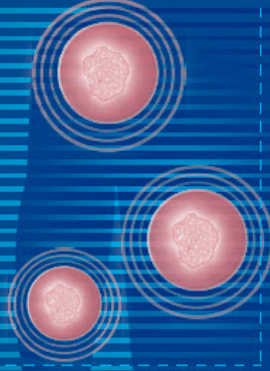
NET WT ½ oz (15 g)

NDC 51672-2140-1

Compare to the active ingredient in Lamisil AT®*

Cures Most Ringworm

Terbinafine Hydrochloride Cream 1% Antifungal Cream



- Relieves Itching, Burning, Cracking and Scaling
- Full Prescription Strength

T174
B75.2
ENG19.53

Cures Most Ringworm

Full Prescription Strength

Terbinafine Hydrochloride Cream 1% Antifungal Cream

NET WT 1/2 oz (15 g)

Terbinafine Hydrochloride Cream 1% Antifungal Cream

NO VARNISH/NO AQ
NO COPY / NO COLOR
THIS FLAP FOR LOT #
AND EXP DATE PRINT

*All trademarks are property of their respective owners. This product is not affiliated with the owners of Lamisil AT®.



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

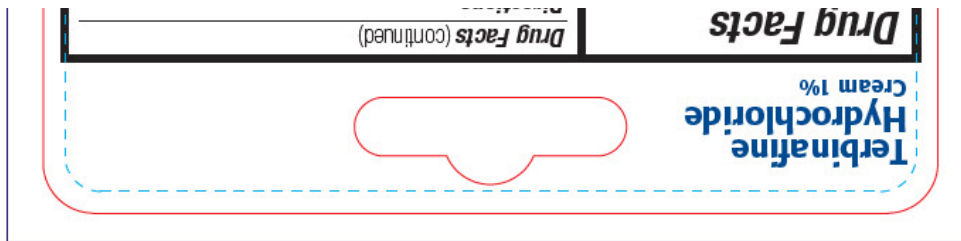


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LPK-8892-0
1118-0
59

<p>Active ingredient Terbinafine hydrochloride 1% Antifungal</p>	<p>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</p>
<p>Warnings For external use only Do not use • on nails or scalp • in or near the mouth or the eyes • for vaginal yeast infections</p>	<p>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.</p>
<p>Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.</p>	
<p>Inactive ingredients: benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol.</p>	
<p>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 clamp for lot number and expiration date</p>	
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<p>Questions? Call 1-866-923-4914</p>	





TERBINAFINE HYDROCHLORIDE

terbinafine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2140
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Terbinafine Hydrochloride (UNII: 012C11ZU6G) (Terbinafine - UNII:G7RIWBS0XP)	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:51672-2140-1	1 in 1 CARTON	02/28/2019	
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 - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2140)

Revised: 3/2021

Taro Pharmaceuticals U.S.A., Inc.