

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 jock itch (tinea cruris)
- relieves itching, burning, cracking and scaling which accompany this condition

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
 - 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

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 - 12 g Tube Carton

Cures Most Jock Itch

Full Prescription Strength

Terbinafine Hydrochloride

Cream 1%

Antifungal

NET WT 0.42 oz (12 g)

NDC 51672-2083-8

Cures Most Jock Itch

Terbinafine Hydrochloride Cream 1% Antifungal

Compare to the active ingredient in Lamisil^{AT}®*



- For Effective Relief of Itching and Burning
- Full Prescription Strength

1174
B75.2
ENG19.53

Cures Most Jock Itch

Full Prescription Strength

Terbinafine Hydrochloride Cream 1% Antifungal

NET WT 0.42 oz (12 g)

Terbinafine Hydrochloride Cream 1% Antifungal

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



LPK-5456-1
0720-1
17



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

* All trademarks are property of their respective owners.

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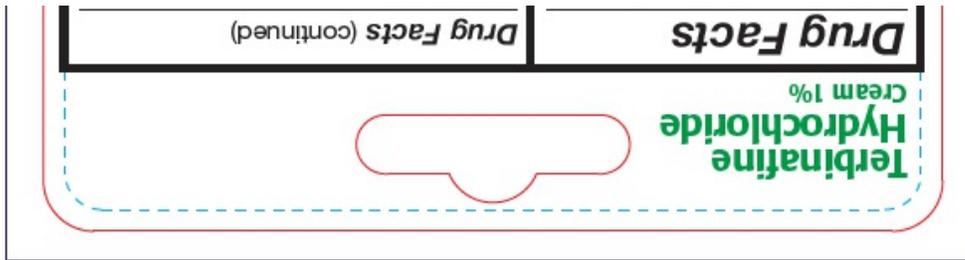
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TERBINAFINE HYDROCHLORIDE

terbinafine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2083
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:51672-2083-8	1 in 1 CARTON	07/02/2007	

1	12 g in 1 TUBE; Type O: 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(51672-2083)

Revised: 7/2020

Taro Pharmaceuticals U.S.A., Inc.