

KAISER PERMANENTE TERBINAFINE HYDROCHLORIDE- terbinafine hydrochloride cream

Kaiser Foundation Hospitals

KAISER PERMANENTE ®

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 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

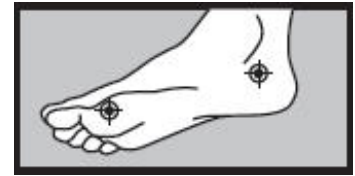
1 week between the toes



2 weeks on the bottom or sides of the foot

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**

Manufactured by

Taro Pharmaceuticals Inc.

Brampton, Ontario, Canada L6T 1C1

Distributed by

Kaiser Foundation Hospitals

Livermore, CA 94551-9756

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

KAISER PERMANENTE®

Terbinafine Hydrochloride Cream 1%

ANTIFUNGAL CREAM

CURES MOST ATHLETE'S FOOT

Compare to the active ingredient in Lamisil AT®*

NET WT 1 OZ (30 g)



Terbinafine Hydrochloride Cream 1%

ANTIFUNGAL CREAM
CURES MOST ATHLETE'S FOOT

Compare to the active ingredient in Lamisil AT®*

NET WT 1 OZ (30 g)

- Relieves Itching & Burning
- Full Prescription Strength

LPK-6413-0
0113-0
M238

T1175



Terbinafine Hydrochloride Cream 1%

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Drug Facts (continued)

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Uses

Terbinafine hydrochloride 1% Antifungal

Drug Facts

Active ingredient

Purpose

Manufactured by
Taro Pharmaceuticals Inc.
Brampton, Ontario, Canada L7R 1C1
Distributed by
Kaiser Foundation Hospitals
Livermore, CA 94551-9756
Made in Canada

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



KAISER PERMANENTE TERBINAFFINE HYDROCHLORIDE

terbinafine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0179-8715
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TERBINAFFINE HYDROCHLORIDE (UNII: 012C11ZU6G) (TERBINAFFINE - UNII:G7RIW8S0XP)	TERBINAFFINE	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:0179-8715-30	1 in 1 CARTON	07/02/2007	06/30/2020
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	06/30/2020

Labeler - Kaiser Foundation Hospitals (053052619)

Registrant - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	manufacture(0179-8715)

Revised: 11/2018

Kaiser Foundation Hospitals