TERBINAFINE HYDROCHLORIDE- terbinafine hydrochloride cream
Proficient Rx LP

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 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.
- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.

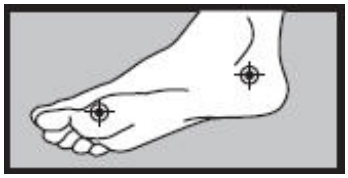
Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

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 (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

- 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.

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

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

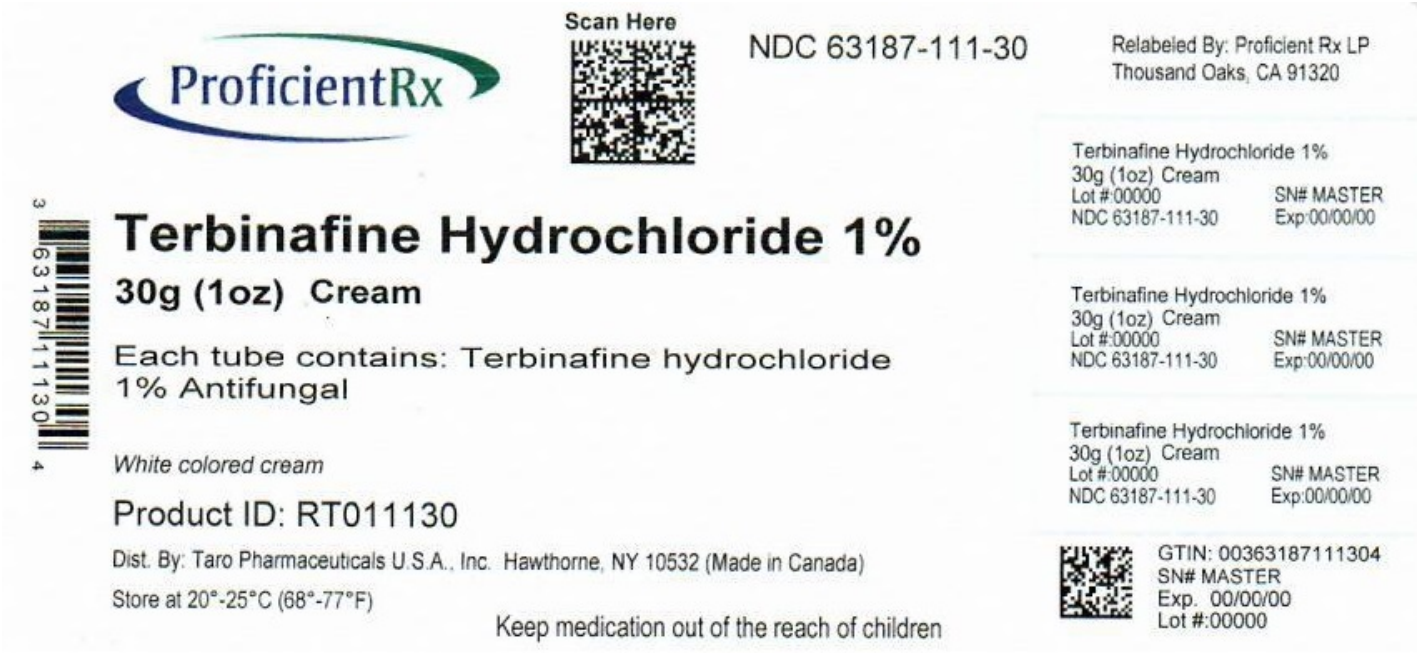
PRINCIPAL DISPLAY PANEL - 30 g Carton

Cures Most Athlete's Foot
Terbinafine Hydrochloride
Cream 1%

Antifungal Cream

Full Prescription Strength

NET WT 1 oz (30 g)



TERBINAFINE HYDROCHLORIDE

terbinafine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63187-111(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:63187-111-15	1 in 1 CARTON	12/01/2018	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:63187-111-30	1 in 1 CARTON	12/01/2018	
2		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 - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-111) , RELABEL(63187-111)