TERBINAFINE HYDROCHLORIDE- terbinafine hydrochloride cream Preferred Pharmaceuticals, 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 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

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: Preferred Pharmaceuticals Inc.

PRINCIPAL DISPLAY PANEL - 30 g Carton

Cures Most Athlete's Foot Terbinafine Hydrochloride Cream 1% Antifungal Cream

Full Prescription Strength

1 week between the toes



2 weeks on the bottom or sides of the foot



NET WT 1 oz (30 g)

Terbinafine Hydrochloride	Pharmaceuticals, Inc.	CAUTION: Federal law PROHIBITS transfer of this drug to any person other thean the patient for whom it was prescribed	Terbinafine Hydrochloride Cream 1 % Qty: Ins: Lot#: Bat#:	
Cream 1% Generic for Lamisil Cream Active Ingredient Terbinafine hydrochloride 1 % Pkg Size: Exp Date: Lot#:	your	vece	Prod# (NDC): Terbinafine Hydrochloride Cream 1 % Qty: Ins: Lot#: Bat#: Prod# (NDC):	
Both: Batch#: Ins: Mfg: Taro Pharm.; Hawthorne, NY Prod#: Warning for external use only. Do rot use on nails or scalp, in or then using this product do age defined the syste. If yet	Directions English externally ay.	Instrucciones Espanol: e amente veo 1. gún lo dirigido doctor	Terbinafine Hydrochloride Cream 1 % Qty: Insurance NDC: Lot#: Bat#:	
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TERBINAFINE HYDR	OCHLORIDE					
terbinafine hydrochloride crea	ım					
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-9814(NDC	:51672-2080)		
Route of Administration	TOPICAL					
Active Ingredient/Active	Moiety					
Ingre	dient Name		Basis of Strength	Strength		
Terbinafine Hydrochloride (UNII: UNII:G7RIW8S0XP)	012C11ZU6G) (Terl		Terbinafine Hydrochloride	1 g in 100 g		
Inactive Ingredients						
	Ingredient Nam	ie	St	rength		
benzyl alcohol (UNII: LKG8494WB	H)					
cetyl alcohol (UNII: 936JST6JCN)						
cetyl palmitate (UNII: 5ZA2S6B08						
isopropyl myristate (UNII: 0RE8K4	•					
polysorbate 60 (UNII: CAL22UVI4M	1)					
water (UNII: 059QF0K00R)						
sodium hydroxide (UNII: 55X04QC32I)						
sorbitan monostearate (UNII: NVZ410H58X)						
stearyl alcohol (UNII: 2KR89I4H1Y)					
Product Characteristics						
Color	WHITE	Score				
Shape		Size				
Flavor		Imprint Code				

CO	ontains			
Pa	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:68788- 9814-1	15 g in 1 TUBE; Type 0: Not a Combination Product	04/05/2012	
M	larketing	Information		
Μ	larketing Marketing Category	Information Application Number or Monograpl Citation	h Marketing Start Date	Marketing End Date

Labeler - Preferred Pharmaceuticals, Inc (791119022)

Registrant - Preferred Pharmaceuticals, Inc (791119022)

Establishment						
Name	Address	ID/FEI	Business Operations			
Preferred Pharmaceuticals, Inc		791119022	RELABEL(68788-9814)			

Revised: 9/2023

Preferred Pharmaceuticals, Inc