ATHLETES FOOT- terbinafine hydrochloride cream Strategic Sourcing Services LLC

Athlete's Foot 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 productdo 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

1 week between the toes

CONTINUES DEFORE 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 ornight) for 1 weekor as directed by a doctor.
- wash hands after each use
- children under 12 years: ask a doctor



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 McKesson One Post Street San Francisco, CA 94104

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

sunmark [®]
athlete's foot cream
terbinafine hydrochloride cream 1%
antifungal cream
FULL PRESCRIPTION STRENGTH
NET WT 1 oz (30 g)

COMPARE TO LAMISIL AT® **ACTIVE INGREDIENT***

Relieves Itching & Burning Cures Most Athlete's Foot

FULL PRESCRIPTION STRENGTH

LPK-6115-0 0708-0 M115

sun mark * athlete's foot cream

terbinafine hydrochloride cream 1%

antifungal cream

FULL PRESCRIPTION STRENGTH

NETWT1 oz (30 g)

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- do not use if sest on tube is broken or is not visible store at controlled room temperature 20°-25°C (88°-77°P) see carlon or tube crimp for lot number and expiration data
 - - Other information

Drug Facts (continued)



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2 weeks on the bottom



- · wash hands after each use
- or as directed by a doctor.

 for jock first and ringworm: apply once a day (morning or right) for 1 week
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Active ingredient Terbinatine hydrochlonde 1%

For external use only

Drug Facts

terbinatine hydrochloride cream 1% athlete's foot cream



ATHLETES FOOT

terbinafine hydrochloride cream

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-790
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
		_

TERBINAFINE HYDROCHLORIDE (UNII: 012C11ZU6G) (TERBINAFINE - UNII:G7RIW8S0XP)

TERBINAFINE 1 g in 100 g

Inactive Ingredients

marcure mg. canonic			
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:49348-790- 72	1 in 1 CARTON	12/12/2012	12/31/2024
1		30 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

ANDA ANDA077511 07/02/2007 12/31/2024

Labeler - Strategic Sourcing Services LLC (116956644)

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	manufacture(49348-790)

Revised: 1/2024 Strategic Sourcing Services LLC