ATHLETES FOOT- terbinafine hydrochloride cream Publix Super Markets Inc.

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 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.

1 week between the toes

- **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

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 PUBLIX SUPER MARKETS, INC. 3300 PUBLIX CORPORATE PARKWAY LAKELAND, FL 33811

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

Publix

athlete'sfootcream

1% TERBINAFINE HYDROCHLORIDE, ANTIFUNGAL CREAM CURES MOST ATHLETE'S FOOT NET WT 1 OZ (30g)



ATHLETES FOOT

terbinafine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-080
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: NVZ 410H58X)			
stearyl alcohol (UNII: 2KR89I4H1Y)			

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:56062-080-	1 in 1 CARTON	02/04/2009	
	L	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 - Publix Super Markets Inc. (006922009)

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(56062-080)	

Revised: 6/2023 Publix Super Markets Inc.