ATHLETE FOOT CREAM- terbinafine hydrochloride cream Beautivity LLC

Initial Drug Listing - Athlete's Foot Cream

Terbinafine Hydrochloride 1%

Antifungal

- cures most athlete's foot (tinea pedis)
- cures most jock itch (tinea crurs) and ringworm (tinea corporis)
- relieves itching, burning, cracking and scaling which accompany these conditions

For external use only

- on nails or scalp
- in or near the mouth or eyes
- for vaginal yeast infections

do not get into eyes, if eye contact occurs, rinse thoroughly with water.

stop use and ask a doctor if too much irritation occurs or gets worse.

if swallowed, call a poison control centre or get medical help right away.

- adults and children 12 years and over
- 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
- Do not use if seal on tube is broken or is not visible.
- Store at 68-77°F (20-25°C)

Allantoin, Glycerin, Propylene Glycol, PCA Dimethicone, Ethylparaben, Glyceryl Stearate, Primary Alcohol Ethoxylate, Alumen, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Polysorbate 80, Aloe Barbadensis Leaf Juice, Parfum

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ATHLETE FOOT CREAM

terbinafine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85398-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TERBINAFINE HYDROCHLORIDE (UNII: 012C11ZU6G) (TERBINAFINE - UNII: G7RIW8S 0XP)	TERBINAFINE HYDROCHLORIDE	1 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
POTASSIUM ALUM (UNII: 1L24V9R23S)		
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)		
GLYCERIN (UNII: PDC6A3C0OX)		
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)		
DIMETHICONE (UNII: 92RU3N3Y10)		
C12-15 PARETH-7 (UNII: 3XY03A79QH)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
ETHYLPARABEN (UNII: 14255EXE39)		
GLYCERYL STEARATE (UNII: 2300U9XXE4)		
ALLANTOIN (UNII: 344S277G0Z)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
ISOHEXADECANE (UNII: 918X1OUF1E)		

Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:85398-006-	60 g in 1 CARTON; Type 0: Not a Combination Product	08/18/2025	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M005	08/18/2025		

Labeler - Beautivity LLC (096573788)

Revised: 7/2025 Beautivity LLC