

**TERBINAFINE HYDROCHLORIDE- terbinafine hydrochloride cream**  
**WALGREEN COMPANY**

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**Terbinafine Hydrochloride**

***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 eyes
- for vaginal yeast infections

**When using this product** 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

**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 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

### **Other information**

**TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE.**

- store at controlled room temperature 20° to 25°C (68° to 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

### **Questions?**

call **1-866-923-4914**

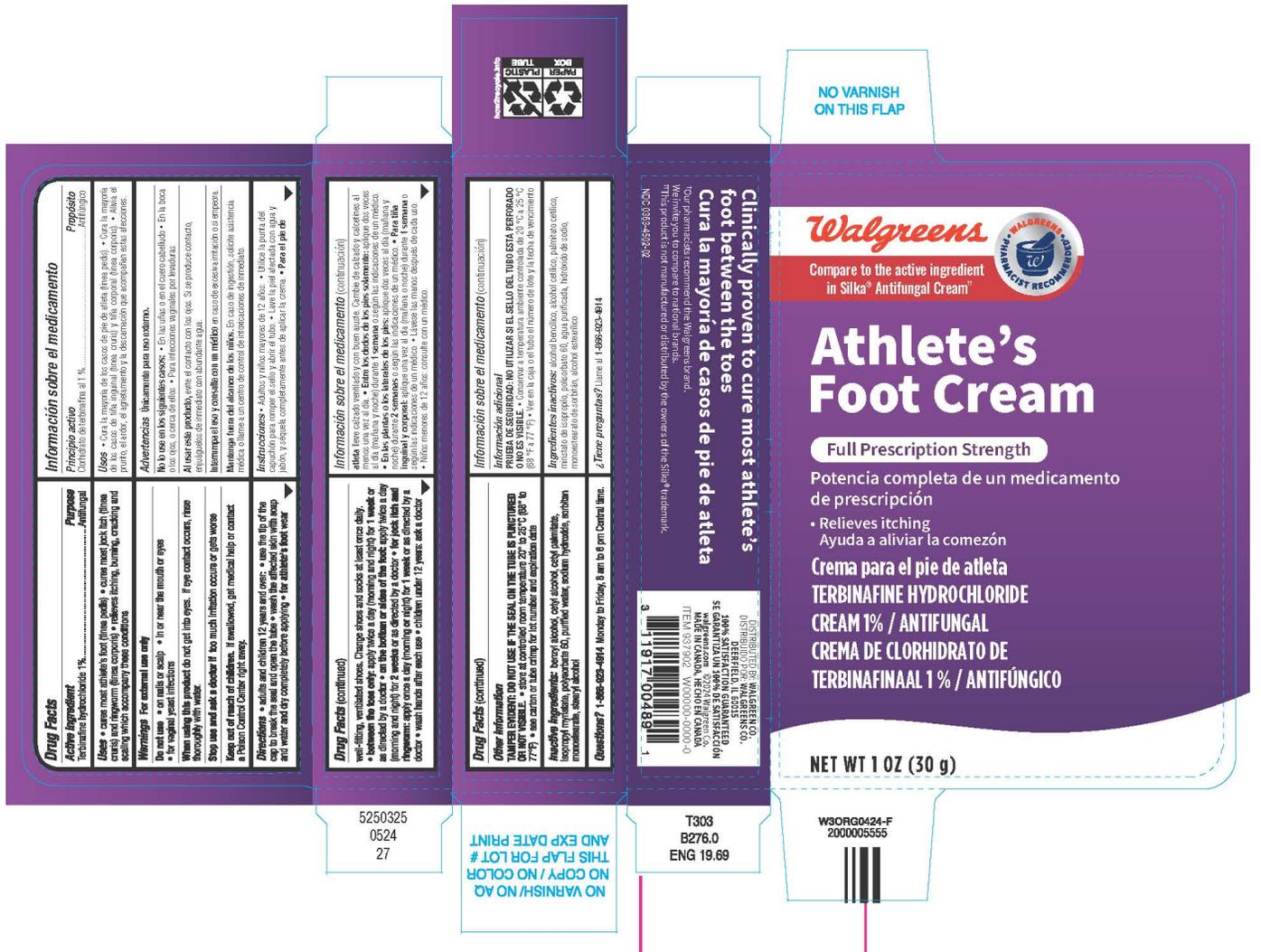
DISTRIBUTED BY: **WALGREEN CO.**  
**DEERFIELD, IL 60015**

### **PRINCIPAL DISPLAY PANEL - 30 g Tube Carton**

Athlete's Foot Cream

TERBINAFINE HYDROCHLORIDE CREAM 1% / ANTIFUNGAL

NET WT 1 OZ (30 g)



# TERBINAFINE HYDROCHLORIDE

terbinafine hydrochloride cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-4502
<b>Route of Administration</b>	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)	

<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4502-02	1 in 1 CARTON	10/25/2023	
1		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	10/25/2023	

**Labeler** - WALGREEN COMPANY (008965063)

### Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(0363-4502)

Revised: 7/2025

WALGREEN COMPANY