

**WALGREENS ATHLETES FOOT- terbinafine hydrochloride cream**  
**Walgreen Company**

-----  
**Walgreens**  
**Athlete's Foot**

**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
- 1 week between the toes

before applying

- **for athlete's footwear** 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



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.

### Questions?

Call **1-866-923-4914**

DISTRIBUTED BY:  
WALGREEN CO.  
200 WILMOT RD.,  
DEERFIELD, IL 60015

**PRINCIPAL DISPLAY PANEL - 15 g Tube Carton**



Walgreens

Athlete's Foot Cream

TERBINAFINE HYDROCHLORIDE 1% / ANTIFUNGAL CREAM

NET WT 0.5 OZ (15 g)

## WALGREENS ATHLETES FOOT

terbinafine hydrochloride cream

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-2080 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

|   |             |                 |
|---|-------------|-----------------|
| <b>TERBINAFINE HYDROCHLORIDE</b> (UNII: 012C11ZU6G) (TERBINAFINE - UNII:G7RIW8S0XP) | TERBINAFINE | 1 g<br>in 100 g |
|---|-------------|-----------------|

### Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| <b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)        |          |
| <b>CETYL ALCOHOL</b> (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)       |          |

### Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | white | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0363-2080-01 | 1 in 1 CARTON                                     | 07/02/2007           |                    |
| 1 |                  | 15 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:0363-2080-02 | 1 in 1 CARTON                                     | 07/02/2007           |                    |
| 2 |                  | 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** - Walgreen Company (008965063)

### Establishment

| Name                      | Address | ID/FEI    | Business Operations    |
|---------------------------|---------|-----------|------------------------|
| Taro Pharmaceuticals Inc. |         | 206263295 | manufacture(0363-2080) |

