

**TERBINAFINE HYDROCHLORIDE- terbinafine hydrochloride cream**  
**Sun Pharmaceutical Industries, Inc.**

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**Terbinafine Hydrochloride**  
**Cream 1%**  
**Antifungal 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 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**

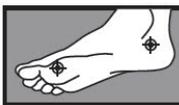
- adults and children 12 years and over:
  - use the tip of the cap to break the seal and open the tube
  - wash the affected skin with soap and water and dry completely before applying

water and dry completely 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



1 week  
between  
the toes



2 weeks on  
the bottom  
or sides of  
the foot

## 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:

**Ohm Laboratories Inc.**

New Brunswick, NJ 08901

Made in Canada

## PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

NDC 51672-2080-2

Full Prescription Strength

FOR ATHLETE'S FOOT

Terbinafine Hydrochloride

Cream 1%  
Antifungal

NET WT 1 oz (30 g)

Compare to the active ingredient in Lamisil<sup>®</sup>AT\*

CLINICALLY PROVEN TO CURE  
MOST ATHLETE'S FOOT BETWEEN THE TOES

# Terbinafine Hydrochloride Cream 1% Antifungal



- Relieves Itching
- Full Prescription Strength

LPK-6119-1  
0220-1  
76

T1175  
B76.2  
ENG19.54

NDC 51672-2080-2

FOR ATHLETE'S FOOT

Full Prescription Strength

# Terbinafine Hydrochloride Cream 1% Antifungal

NET WT 1 oz (30 g)

Terbinafine Hydrochloride Cream 1% Antifungal

\* All trademarks are property of their respective owners.

Distributed by: Taro Pharmaceuticals U.S.A., Inc.  
Hawthorne, NY 10532

**TARO**  
TARO is a registered trademark of  
Taro Pharmaceuticals U.S.A., Inc.  
Made in Canada



NO VARNISH ON THIS FLAP

NO VARNISH ON THIS FLAP

<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Terbinafine hydrochloride 1% Antifungal</p> <p><b>Purpose</b> Antifungal</p>		<p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• cures most athlete's foot (tinea pedis)</li> <li>• cures most jock itch (tinea cruris) and ringworm (tinea corporis)</li> <li>• relieves itching, burning, cracking and scaling which accompany these conditions</li> </ul>	
<p><b>Warnings</b></p> <p>For external use only</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>• on nails or scalp</li> <li>• in or near the mouth or eyes</li> <li>• for vaginally used antifungals</li> </ul> <p><b>When using this product do not get into eyes.</b> If eye contact occurs, rinse thoroughly with water.</p> <p><b>Stop use and ask a doctor if:</b> too much irritation occurs or gets worse</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>		<p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• use the tip of the cap to break the seal and open the tube</li> <li>• adults and children 12 years and over</li> </ul>	
<p><b>Other information</b></p> <p><b>TAMPER EVIDENCE DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE</b></p> <ul style="list-style-type: none"> <li>• store at controlled room temperature 20° to 25°C (68° to 77°F)</li> <li>• see carton or tube or crimp for lot number and expiration date</li> </ul> <p><b>Inactive ingredients:</b> benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polyisobutene 60, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol</p> <p><b>Questions?</b> call 1-866-923-4914</p>		<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>• wash the affected skin with soap and water and dry completely before applying</li> <li>• for athlete's foot wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.</li> <li>• be between the toes only:</li> <li>• apply twice a day (morning and night) for 1 week or as directed by a doctor</li> <li>• on the bottom or sides of the foot</li> <li>• apply twice a day (morning and night) for 2 weeks or as directed by a doctor</li> <li>• for lock itch and ringworm</li> <li>• apply twice a day (morning or night) for 1 week or as directed by a doctor</li> <li>• wash hands after each use</li> <li>• children under 12 years: ask a doctor</li> <li>• children under 12 years: ask a doctor</li> </ul>	



Terbinafine Hydrochloride Cream 1%

# PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

NDC 51672-2080-2

**ohm**  
LABORATORIES INC.  
a SUN PHARMA company

CLINICALLY PROVEN TO CURE  
MOST ATHLETE'S FOOT BETWEEN THE TOES

## Terbinafine Hydrochloride Cream 1%

Antifungal

Compare to  
the active ingredient  
in Lamisil<sup>AT</sup>®\*



- Relieves Itching
- Full Prescription Strength

5267/052  
1125  
76

T175  
B76.2  
ENG19.54

FOR ATHLETE'S FOOT

Full Prescription Strength

## Terbinafine Hydrochloride Cream 1%

Antifungal

NET WT 1 oz (30 g)

NO VARNISH/NO AQ  
NO COPY / NO COLOR  
THIS FLAP FOR LOT #  
AND EXP DATE PRINT

Terbinafine  
Hydrochloride  
Cream 1%  
Antifungal

Distributed by:  
**Ohm Laboratories Inc.**  
New Brunswick, NJ 08901  
Made in Canada

\*OHM and OHM Logo are  
trademarks of Ohm Laboratories,  
Inc. All other trademarks are the  
property of their respective owners.



NO VARNISH  
ON THIS FLAP

NO VARNISH  
ON THIS FLAP

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# TERBINAFINE HYDROCHLORIDE

terbinafine hydrochloride cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51672-2080
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TERBINAFINE HYDROCHLORIDE</b> (UNII: 012C11ZU6G) (TERBINAFINE - UNII:G7RIW8S0XP)	TERBINAFINE HYDROCHLORIDE	1 g 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:51672-2080-1	1 in 1 CARTON	07/02/2007	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-2080-2	1 in 1 CARTON	07/02/2007	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:51672-2080-8	1 in 1 CARTON	07/02/2007	
3		12 g in 1 TUBE; Type 0: Not a Combination Product		

4	NDC:51672-2080-9	1 in 1 CARTON	07/02/2007	
4		24 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:51672-2080-6	1 in 1 CARTON	07/02/2007	
5		45 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:51672-2080-3	1 in 1 CARTON	07/02/2007	
6		60 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:51672-2080-4	1 in 1 CARTON	04/24/2017	
7		15 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** - Sun Pharmaceutical Industries, Inc. (146974886)

## Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(51672-2080)

Revised: 2/2026

Sun Pharmaceutical Industries, Inc.