

**ATHLETES FOOT- butenafine hydrochloride cream**  
**Taro Pharmaceuticals U.S.A., inc.**

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**Athlete's Foot Cream**

**Drug Facts**

**Active ingredient**

Butenafine hydrochloride 1%

**Purpose**

Antifungal

**Uses**

- cures most athlete's foot between the toes. Effectiveness on the bottom or sides of foot is unknown.
- cures most jock itch and ringworm
- 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 irritation 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 between the toes:** apply to affected skin between and around the toes twice a day for 1 week (morning and night), or once a day for 4 weeks, or as directed by a doctor. Wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.

**Apply between and around the toes**



**1 week twice a day or 4 weeks once a day**

- **for jock itch and ringworm:** apply once a day to affected skin for 2 weeks or as directed by a doctor.
- wash hands after each use

- children under 12 years: ask a doctor

**Other information**

- do not use if seal on tube is broken or not visible
- store between 20° to 25° C (68° to 77° F)

**Inactive ingredients**

benzyl alcohol, cetyl alcohol, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, trolamine, white petrolatum

**Questions?**

Call 1-866-923-4914

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

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

*Clinically Proven to Cure Most Athlete's Foot between the Toes*

**Butenafine**

**Hydrochloride Cream 1%**

**Antifungal**

**NET WT 15 g (0.53 oz)**

NDC 51672-2100-1

Compare to the active ingredient in Lotrimin Ultra®\*

# Clinically Proven to Cure Most Athlete's Foot between the Toes

Contains the Drug: BUTENAFINE HYDROCHLORIDE

- Prescription Strength
- Relieves Itching, Burning and Cracking

**1 Week**  
Treatment Option  
For Athlete's Foot  
See Directions

T-174  
B75.2  
ENG19.53

## Butenafine Hydrochloride Cream 1% Antifungal

Clinically Proven to Cure Most Athlete's Foot between the Toes

# Butenafine Hydrochloride Cream 1% Antifungal

NET WT 15 g (0.53 oz)

Butenafine Hydrochloride Cream 1%  
Antifungal

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

\*All trademarks are property of their respective owners.  
This product is not affiliated with the makers/owners of Lotrimin Ultra®.



Distributed by: Taro Pharmaceuticals U.S.A., Inc.  
Hawthorne, NY 10532  
TARO is a registered trademark of  
Taro Pharmaceuticals U.S.A., Inc.  
Made in Canada

LPK-7025-0  
1016-0  
M51

NO VARNISH  
ON THIS FLAP

Butenafine hydrochloride 1% Antifungal

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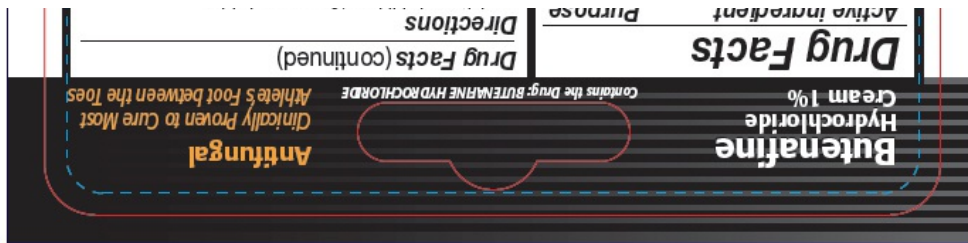
**Warnings**  
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Do not use  
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• in or near the mouth or the eyes  
• for vaginal yeast infections  
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Stop use and ask a doctor if too much irritation occurs or irritation gets worse  
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• wash hands after each use  
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**Inactive ingredients**  
benzyl alcohol, cetyl alcohol, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol diacetate, purified water, sodium benzoate, stearic acid, tolamine, white petrolatum

**Questions?** Call 1-866-923-4914





## ATHLETES FOOT

butenafine hydrochloride cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51672-2100
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Butenafine Hydrochloride</b> (UNII: R8 XA2029 ZI) (Butenafine - UNII:9 1Y494NL0 X)	Butenafine Hydrochloride	10 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>benzyl alcohol</b> (UNII: LKG8494WBH)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>ceteth-23</b> (UNII: 495CTZ441V)	
<b>propylene glycol dicaprylate</b> (UNII: 581437HWX2)	
<b>water</b> (UNII: 059QF0K00R)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>stearic acid</b> (UNII: 4ELV7Z65AP)	
<b>trolamine</b> (UNII: 9O3K93S3TK)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	

### 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:51672-2100-8	1 in 1 CARTON	11/17/2017	
1		12 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-2100-1	1 in 1 CARTON	11/17/2017	
2		15 g in 1 TUBE; Type 0: Not a Combination Product		

3	NDC:51672-2100-9	1 in 1 CARTON	11/17/2017	
3		24 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:51672-2100-2	1 in 1 CARTON	11/17/2017	
4		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	ANDA205181	11/17/2017	

**Labeler** - Taro Pharmaceuticals U.S.A., inc. (145186370)

## Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2100)

Revised: 11/2017

Taro Pharmaceuticals U.S.A., inc.