

ATHLETES FOOT- butenafine hydrochloride cream
Sun Pharmaceutical Industries, Inc.

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.

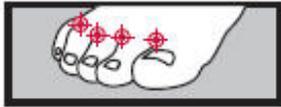
Stop use and ask a doctor if too much irritation occurs or irritation gets worse

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



- **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

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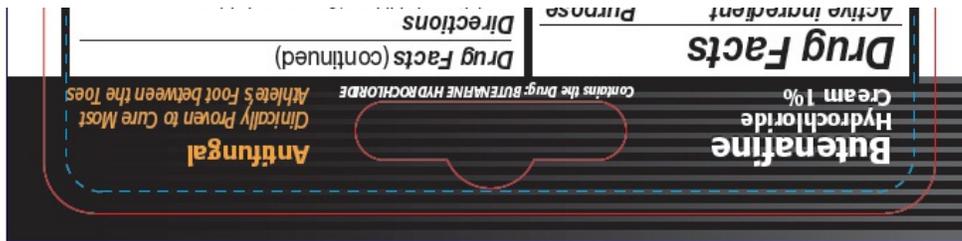
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ATHLETES FOOT

butenafine hydrochloride cream

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BUTENAFINE HYDROCHLORIDE (UNII: R8XA2029ZI) (BUTENAFINE - UNII:91Y494NL0X)	BUTENAFINE HYDROCHLORIDE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETETH-23 (UNII: 495CTZ441V)	
PROPYLENE GLYCOL DICAPRYLATE (UNII: 581437HWX2)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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 - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(51672-2100)

Revised: 7/2025

Sun Pharmaceutical Industries, Inc.