# ATHLETES FOOT- butenafine hydrochloride cream TOPCO ASSOCIATES LLC

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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 **1-888-423-0139** 

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007

## PRINCIPAL DISPLAY PANEL - 12 g Tube Carton

 $TopCare_{\mathbb{R}}$  health $_{TM}$ 

PRESCRIPTION STRENGTH

Athlete's Foot Cream Ultra

BUTENAFINE HYDROCHLORIDE CREAM 1% • ANTIFUNGAL

NET WT 0.42 OZ (12 g)

**OUR PHARMACISTS** 

RECOMMEND •

NDC 36800-049-01

COMPARE TO LOTRIMIN ULTRA® ACTIVE INGREDIENT\*

## Athlete's Foot Cream Ultra

BUTENAFINE HYDROCHLORIDE CREAM 1% • ANTIFUNGAL

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

#### **RELIEVES:**

- · Itching · Burning
- Cracking Scaling

1 Week Treatment Option for Athlete's Foot

SEE DIRECTIONS

CONTAINS THE DRUG: BUTENAFINE HYDROCHLORIDE

TopCare.

## PRESCRIPTION STRENGTH

# **Athlete's Foot Cream Ultra**

**BUTENAFINE HYDROCHLORIDE CREAM 1% • ANTIFUNGAL** 

NET WT 0.42 OZ (12 g)

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ENG19.53

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ELK GROVE VILLAGE, IL 60007

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QUESTIONS? 1-888-423-0139

topcare@topco.com

www.topcarebrand.com MADE IN CANADA Visit here for more information: http://topbrnds.com/48zr65

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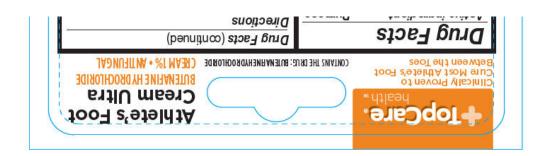
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## ATHLETES FOOT

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-049
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Butenafine Hydrochloride (UNII: R8 XA2029 ZI) (Butenafine - UNII:91Y494NL0 X)	Butenafine Hydrochloride	10 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
benzyl alcohol (UNII: LKG8494WBH)			
cetyl alcohol (UNII: 936JST6JCN)			
glycerin (UNII: PDC6A3C0OX)			
Glyceryl Stearate Se (UNII: FCZ5MH785I)			
<b>CETETH-23</b> (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			

P	ackaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:36800-049-01	1 in 1 CARTON	12/12/20 17	
1		12 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 - TOPCO ASSOCIATES LLC (006935977)

Revised: 8/2018 TOPCO ASSOCIATES LLC