

LOTRIMIN ULTRA- butenafine hydrochloride cream
Bayer Healthcare LLC.

Lotrimin Ultra ®

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.
- relieves itching, burning, cracking, and scaling which accompany this condition

Warnings

For external use only

- 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:**
 - wash the affected skin with soap and water and dry completely before applying
 - to open the applicator, twist the base to the ON position. Squeeze tube to dispense cream.
 - **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.
 - wipe applicator tip with a tissue and close the applicator by twisting the base to the OFF position

- wash hands after each use
- children under 12 years: ask a doctor

Other information

- 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?

1-866-360-3266 or visit us at www.lotrimin.com

LOTRIMIN ULTRA ®

BUTENAFINE HYDROCHLORIDE CREAM 1% ANTIFUNGAL

NET WT 20g (0.70 OZ)



BRIEF FACTS INFO		
Updated 5/1/2010		
CATEGORY	REQUIRED	ACTUAL ON FILE
Drug Facts Table	all pgs ¹	8 pgs
Drug Facts Continued		-
Headings ²	all pgs bold italic ³	8 pgs
Color/headers	all pgs	8 pgs
Body text	all pgs	8 pgs
Box/tables	5 pgs	5 pgs
Loading	all/5 pgs	8/5 pgs
Headlines	0/5 pgs rule	0/5 pgs
Box and Bottoms	all/5 pgs rule	-
Chemicals per facts	no more than 252	252

¹ Headings only to be selected 2pgs larger than body text

² Headings only to be selected 2pgs larger than body text

³ Headings only to be selected 2pgs larger than body text

LOTRIMIN ULTRA
butenafine hydrochloride cream

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:11523-0082
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
BUTENAFINE HYDROCHLORIDE (UNII: R8XA2029ZI) (BUTENAFINE - UNII:91Y494NLOX)			BUTENAFINE HYDROCHLORIDE	1 g in 100 g
Inactive Ingredients				
Ingredient Name				Strength
STEARIC ACID (UNII: 4ELV7Z65AP)				
TROLAMINE (UNII: 9O3K93S3TK)				
GLYCERIN (UNII: PDC6A3C0OX)				
WHITE PETROLATUM (UNII: B6E5W8RQJ4)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
CETETH-23 (UNII: 495CTZ441V)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
PROPYLENE GLYCOL DICAPRYLATE (UNII: 581437HWX2)				
Product Characteristics				
Color	white (white to off white)		Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-0082-1	1 in 1 CARTON	12/20/2021	
1		20 g in 1 TUBE, WTH APPLICATOR; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

CRITICAL FACTS INFO (updated 5/10/10)		
CATEGORY	REQUIRED	ACTUAL, IN
Congress Factbook	> 8 yrs. ^{1,2}	8 yrs.
Congress Factbook Continued	8 yrs.	-
Headings ³	8 yrs./bold italic ⁴	8 yrs.
Subheadings	> 8 yrs.	8 yrs.
Body Text	> 8 yrs.	8 yrs.
Markets	5 yrs.	5 yrs.
Loading	> 8 yrs.	8.5 yrs.
Headlines	0.5 yrs./bold	0.5 yrs.
Box and Bulleted	> 8.5 yrs./rule	9 yrs.
Characters Per line	No more than 33	33

¹ Headings go to at least 3 yrs. larger than body text.
² Headlines go to at least 3 yrs. larger than all other type can survive 30%
³ 12pt. Bookends, 10pt. font

Labeler - Bayer Healthcare LLC. (112117283)

Revised: 12/2025

Bayer Healthcare LLC.