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)


LOTRIMIN ULTRA
PRESCRIPTION STRENGTH
Contains the Drug: BUTENAFINE HYDROCHLORIDE
LOTRIMIN
ULTRA
BUTENAFINE HYDROCHLORIDE CREAM 1% ANTIFUNGAL
PRESCRIPTION STRENGTH
NO TOUCH APPLICATOR
CLINICALLY PROVEN TO CURE MOST ATHLETE'S FOOT BETWEEN THE TOES
RELIEVES
ITCHING
BURNING
CRACKING
1 WEEK
TREATMENT OPTION
FOR ATHLETE'S FOOT
SEE DIRECTIONS
NET WT 20g (0.70 OZ)
Actual size
Contains the Drug: BUTENAFINE HYDROCHLORIDE
LOTRIMIN ULTRA
PRESCRIPTION STRENGTH
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Apply between and around the toes
1 week twice a day or 4 weeks once a day
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store between 20° to 25°C (68° to 77°F)
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Questions? 1-866-360-3266 or visit us at www.lotrimin.com
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Product of Japan
Bayer
00000000
Recyclable Carton
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Actual Size 100%

FDA00439-3

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	9 pt
Drug Facts Continued	8 pt	-
Headings*	8 pt-bold italic*	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	5 pt
Leading	≥0.5 pt	0.5 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines†	>0.5 pt rule	1 pt
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP
† FDA Recommends 2.5pt rule

Approved by gebbl on 17-Dec-2020 18:31

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:91Y494NL0X)	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, WITH APPLICATOR; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Actual Size 100%

FDA00439-3

Approved by gebbl on 17-Dec-2020 18:31

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021307	12/20/2021	

Labeler - Bayer Healthcare LLC. (112117283)

Revised: 11/2023 Bayer Healthcare LLC.