LOTRIMIN ULTRA ANTIFUNGAL- butenafine hydrochloride cream
Bayer HealthCare LLC.

Lotrimin Ultra ®

Antifungal

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.
  - **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, diethanolamine, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

Questions?

866-360-3226

Distributed by MSD Consumer Care, Inc., PO Box 377, Memphis, TN 38151 USA, a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ USA.

PRINCIPAL DISPLAY PANEL - 30g Tube Carton

LOTRIMIN ULTRA®

butenafine hydrochloride cream 1%
ANTIFUNGAL
NET WT 30g (1.1 OZ)

Contains the Drug: BUTENAFINE HYDROCHLORIDE

LOTRIMIN ULTRA®

PRESCRIPTION STRENGTH

Relieves: ☑ Itching ☑ Burning ☑ Cracking

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

NDC 11523-7154-3

LOTRIMIN ULTRA®

butenafine hydrochloride cream 1% ANTIFUNGAL

LOTRIMIN ULTRA®

butenafine hydrochloride cream 1% ANTIFUNGAL NET WT 30g (1.1 OZ)

S-05-44

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Questions? 1-866-360-3226 or visit us at www.lotrimin.com

Recyclable Carton

PRESCRIPTION STRENGTH

LOTRIMIN ULTRA®

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www.lotrimin.com

LOTRIMIN ULTRA ANTIFUNGAL

butenafine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11523-7154
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)	
DIETHANOLAMINE (UNII: AZE05TDV2V)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETETH-23 (UNII: 495CTZ441V)	
PROPYLENE GLYCOL DICAPRYLATE (UNII: 581437HWX2)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PETROLATUM (UNII: 4T6H12BN9U)	

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:11523-7154-1	1 in 1 CARTON	02/22/2002	09/01/2017
1		12 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11523-7154-2	1 in 1 CARTON	02/22/2002	09/01/2017
2		24 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:11523-7154-3	1 in 1 CARTON	02/22/2002	09/01/2017
3		30 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:11523-7154-4	1 in 1 CARTON	02/01/2002	09/01/2017
4		15 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
NDA	NDA021307	09/23/1993	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 2/2017 Bayer HealthCare LLC.