LOTRIMIN ULTRA JOCK ITCH- butenafine hydrochloride cream
Bayer Healthcare LLC.

Lotrimin Ultra ®

Jock Itch

Drug Facts

Active ingredient

Butenafine hydrochloride 1%

Purpose

Antifungal

Uses

- cures most jock itch
- relieves itching, burning, cracking, and scaling which accompany this condition

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 over:
  - 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
  - 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

Distributed by Bayer HealthCare LLC, Whippany, NJ 07981

PRINCIPAL DISPLAY PANEL - 12 g Tube Carton

LOTRIMIN ULTRA®

butenafine hydrochloride cream 1% ANTIFUNGAL NET WT 12g (0.42 OZ)

LOTRIMIN ULTRA JOCK ITCH

butenafine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11523-4339

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
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)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

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:11523-4339-1	1 in 1 CARTON	02/22/2002	
1		12 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11523-4339-2	1 in 1 CARTON	02/22/2002	
2		15 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:11523-4339-3	1 in 1 CARTON	09/26/2023	
3		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

NDA	NDA021307	02/22/2002	

Labeler - Bayer Healthcare LLC. (112117283)

Revised: 9/2023 Bayer Healthcare LLC.