JOCK ITCH- butenafine hydrochloride cream
Taro Pharmaceuticals U.S.A., inc.

Jock Itch Cream

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 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
  - 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), propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, trolamine, white petrolatum

Questions?

Call **1-866-923-4914**

Distributed by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

Clinically Proven to Cure Most Jock Itch

Butenafine
Hydrochloride Cream 1%

Antifungal
NET WT 15 g (0.53 oz)

NDC 51672-2101-1

Compare to the active ingredient in Lotrimin Ultra® Jock Itch*

Clinically Proven to Cure Most Jock Itch

Contains the Drug: BUTENAFINE HYDROCHLORIDE

- *Prescription Strength*
- *Relieves Itching, Burning and Chafing*

Butenafine Hydrochloride Cream 1%

Antifungal

T174
B75.2
ENG19.53

NO VARNISH/ NO AQ
NO COPY / NO COLOR
THIS FLAP FOR LOT #
AND EXP DATE PRINT

Clinically Proven to Cure Most Jock Itch

Butenafine Hydrochloride Cream 1%

Antifungal

NET WT 15 g (0.53 oz)

Butenafine Hydrochloride Cream 1% Antifungal

LPK-7033-0
1016-0
M53

*All trademarks are property of their respective owners.
This product is not affiliated with the makers/owners of Lotrimin Ultra®.

Distributed by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532
TARO is a registered trademark of
Taro Pharmaceuticals U.S.A., Inc.
Made in Canada.

NO VARNISH ON THIS FLAP

Drug Facts

Active ingredient — **Purpose**
Butenafine hydrochloride 1% ..... 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.

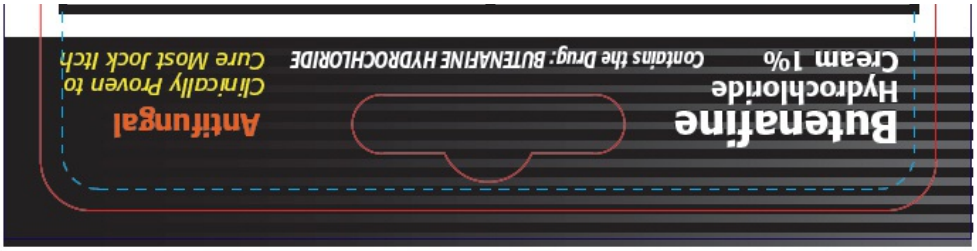
Drug Facts (continued)

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
  - 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 1-866-923-4914



JOCK ITCH

butenafine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2101
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)	
glycerin (UNII: PDC6A3C0OX)	
glyceryl stearate SE (UNII: FCZ5MH785I)	
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)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51672-2101-8	1 in 1 CARTON	11/17/2017	
1		12 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-2101-1	1 in 1 CARTON	11/17/2017	

2		15 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:51672-2101-9	1 in 1 CARTON	11/17/2017	
3		24 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:51672-2101-2	1 in 1 CARTON	11/17/2017	
4		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
ANDA	ANDA205181	11/17/2017	

Labeler - Taro Pharmaceuticals U.S.A., inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2101)

Revised: 11/2017 Taro Pharmaceuticals U.S.A., inc.