

CLOTRIMAZOLE- clotrimazole solution

Taro Pharmaceuticals U.S.A., Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Clotrimazole Topical Solution USP, 1%

Drug Facts

Active ingredient

Clotrimazole USP, 1%

Purpose

Antifungal

Uses

- cures most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis)
- effectively relieves
- itching
- cracking
- burning
- discomfort

which can accompany these conditions

Warnings

For external use only

Ask a doctor before use

- on children under 2 years of age

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- This product is not effective on the scalp or nails For best results, follow directions and continue treatment for length of time indicated. For athlete's foot and ringworm: use daily for 4 weeks. For jock itch: use daily for 2 weeks.
- clean the affected area and dry thoroughly
- apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor

- supervise children in the use of this product

For athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes; change shoes and socks at least once daily

Other information

- **Store at 20° to 25°C (68° to 77°F)** [see USP Controlled Room Temperature].

Inactive ingredient

polyethylene glycol 400

Questions?

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

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 10 mL Bottle Carton

Compare to the
active ingredient
in Lotrimin[®] AF*

Cures Most Athlete's Foot

Athlete's Foot Solution

Clotrimazole Topical Solution USP, 1%

Antifungal

- *Relieves Itching & Burning*
- *Greaseless,
Nonstaining*

**10 mL
(\square fl oz)**

Compare to the
active ingredient
in Lotrimin® AF*

Cures Most Athlete's Foot

Athlete's Foot Solution

Clotrimazole Topical Solution USP, 1%

Antifungal

- *Relieves Itching & Burning*
- *Greaseless,
Nonstaining*

10 mL
(1/3 fl oz)

Cures Most
Athlete's Foot

Antifungal

Athlete's Foot Solution

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Inactive ingredient polyethylene glycol 400

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

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Taro Pharmaceuticals U.S.A., Inc.
Made in Canada.

PK-1627-4 0416-4



CLOTRIMAZOLE

clotrimazole solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2037
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
polyethylene glycol 400 (UNII: B697894SGQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2037-1	1 in 1 CARTON	05/01/1996	
1		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333C	05/01/1996	

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2037)

Revised: 4/2017

Taro Pharmaceuticals U.S.A., Inc.