

CLOTRIMAZOLE 1% ATHLETES FOOT- clotrimazole cream

CVS Pharmacy

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 USP, 1%

Athlete's Foot

Drug Facts

Active ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

- cures most athlete's foot, jock itch and ringworm
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions

Warnings

For external use only

Do not use on children under 2 years of age unless directed by a doctor.

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 or 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

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- 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 and change socks at least once daily
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition persists longer, ask a doctor
- this product is not effective on the scalp or nails

Other information

- To open: unscrew cap, use the pointed end of cap to puncture seal.
- store between 20° - 25°C (68° - 77°F)

- see carton or tube crimp for lot number and expiration date

Inactive ingredients

benzyl alcohol (1%), cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sorbitan monostearate

Questions?

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

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

**CVS
pharmacy™**

Compare to the active
ingredient in Lotrimin® AF*

***CLOTRIMAZOLE CREAM USP, 1%
ANTIFUNGAL CREAM***

CURES MOST ATHLETE'S FOOT

NET WT 1 OZ (28.4 g)

CVS
pharmacy™

NDC 59779-305-02
Compare to the active
ingredient in Lotrimin® AF*

CURES MOST ATHLETE'S FOOT



**Relieves itching,
burning, cracking
& scaling**

LPK-1441-8
1013-8
M129



Actual Size

CVS
pharmacy™

Compare to the active
ingredient in Lotrimin® AF*

**CLOTRIMAZOLE CREAM USP, 1%
ANTIFUNGAL CREAM**
CURES MOST ATHLETE'S FOOT

NET WT 1 OZ (28.4 g)

CVS
pharmacy™

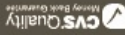
**CLOTRIMAZOLE
CREAM USP, 1%
ANTIFUNGAL
CREAM**
CURES MOST
ATHLETE'S FOOT

T30



Drug Facts (continued)
Active ingredients: benzyl alcohol (1%), cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polyisobutene 60, purified water, sorbitan monolaurate.
Call 1-866-823-4914

NO COPY / NO COLOR
THIS FLAP FOR LOT #
AND EXPIRE DATE PRINT



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CVS Pharmacy, Inc.
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Wood Dale, IL 60195
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V-11653
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Member Public Guarantee

Drug Facts
Active ingredient Clotrimazole 1% Antifungal
Uses • cures most athlete's foot, jock itch and ringworm
• relieves itching, burning, cracking, scaling and discoloration which accompany these conditions
Warnings
For external use only
Do not use on children under 2 years of age unless directed by a doctor.
When using this product avoid contact with eyes.
Stop use and ask doctor if • Irritation occurs
• there is no improvement within 4 weeks (for athlete's foot or 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
• wash affected area and dry thoroughly (morning and night)
• apply a thin layer over affected area twice daily (morning and night)
• separate children in the use of this product
• for athlete's foot, pay special attention to spaces between the toes, wear well-fitting, ventilated shoes and change socks at least once daily
• for athlete's foot and ringworm, use daily for 4 weeks for jock itch, use daily for 2 weeks
• if condition persists longer, ask a doctor • this product is not effective on the scalp or nails
Other information
• To open: unscrew cap, use the pointed end of cap to puncture seal.
• Store between 20° - 25°C (68° - 77°F) • see carton or tube crimp for lot number and expiration date

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CLOTRIMAZOLE 1% ATHLETES FOOT

clotrimazole cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59 779-305 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------------------|-------------------|--------------|
| Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65) | Clotrimazole | 10 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------------|----------|
| benzyl alcohol (UNII: LKG8494WBH) | |
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| cetyl esters wax (UNII: D072FFP9GU) | |
| octyldodecanol (UNII: 461N1O614Y) | |
| polysorbate 60 (UNII: CAL22UVI4M) | |
| water (UNII: 059QF0K00R) | |
| sorbitan monostearate (UNII: NVZ4I0H58X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:59779-305-01 | 1 in 1 CARTON | | |
| 1 | | 15 g in 1 TUBE | | |
| 2 | NDC:59779-305-02 | 1 in 1 CARTON | | |
| 2 | | 30 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part333C | 08/31/1993 | |

Labeler - CVS Pharmacy (062312574)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|------------------------|
| Taro Pharmaceuticals Inc. | | 206263295 | MANUFACTURE(59779-305) |