CLOTRIMAZOLE- clotrimazole cream TOP CARE (Topco Associates LLC)

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 Vaginal Cream, USP

Drug Facts

Active ingredients

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Clotrimazole, USP 1%
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Purpose

Antifungal

Uses

- treats most athlete's foot, jock itch, and ringworm
- relieves itching, burning, cracking, scaling, and discomfort

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 the eyes.

Stop use and ask a doctor if

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

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- wash 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, and change shoes and 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 lasts longer, contact a doctor
- this product is not effective on the scalp or nails

Other information

- store at room temperature 20°-25°C (68°-77°F)
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sodium phosphate monobasic, sorbitan monostearate

Question or comments?

Call toll free 1-888-423-0139

Principal display panel

COMPARE TO LOTRIMIN® AF ATHLETE'S FPPT CREAM ACTIVE INGREDIENT*

Athlete's Foot Cream

Cure Most Athlete's Foot

RELIEVES:

- Itching
- Burning
- Cracking
- Scaling
- Proven Clinically Effective in the Treatment of Most Athlete's Foot
- Soothes Itching and Burning

NET WT. OZ (g)

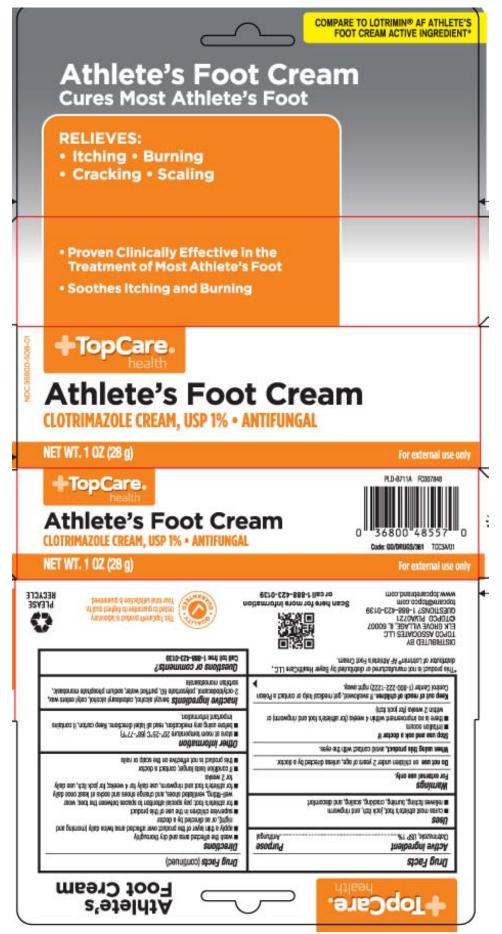
*This product is not manufactured or distributed by Bayer HealthCare LLC., distributor of Lotrimin® AF Athlete's Foot Cream.

DISTRIBUTED BY

TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007 www.topcarebrand.com

Package label



TOPCARE HEALTH Athlete's Foot Cream

CLOTRIMAZOLE

clotrimazole cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-508	
Route of Administration	VAGINAL			

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: 059QF0KO0R)		
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)		
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36800-508- 01	1 in 1 CARTON	09/30/2021		
1		28 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	
OTC monograph final	part333C	09/30/2021		

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 12/2022 TOP CARE (Topco Associates LLC)