

ANTIFUNGAL - clotrimazole cream
Encube Ethicals Private Limited

Clotrimazole Cream-Antifungal

ACTIVE INGREDIENT(S)

Clotrimazole, USP 1%

PURPOSE

Antifungal

USE(S)

- cures 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 DOCTOR IF

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot 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°C to 25°C (68°F to 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

QUESTIONS OR COMMENTS?

Call 1-833-285-4151

PRINCIPAL DISPLAY PANEL

Athlete's Foot Cream

Clotrimazole Cream USP, 1% (Antifungal)

NET WT. 0.5 OZ (14 g)

NDC 21922-094-04



Athlete's Foot Cream

ANTIFUNGAL
Cures most athlete's foot
Relieves itching, burning, cracking & scaling

Clotrimazole Cream USP, 1%

Compare to the active ingredient in **Lotrimin® AF Athlete's Foot Cream***

NDC 21922-094-04

Compare to the active ingredient in **Lotrimin® AF Athlete's Foot Cream***

Athlete's Foot Cream

Clotrimazole Cream USP, 1%

NET WT. 0.5 OZ (14 g)

NDC 21922-094-04



Athlete's Foot Cream

ANTIFUNGAL
Cures most athlete's foot
Relieves itching, burning, cracking & scaling

Clotrimazole Cream USP, 1%

NET WT. 0.5 OZ (14 g)

EMBOSSING AREA

Mfg. Lic. No.: 361

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



Manufactured by:
Encube Ethicals Pvt. Ltd.
Plot No. C-1, Madkaim
Industrial Estate, Madkaim,
Post: Marcol, Ponda,
Goa - 403 404, India.

Distributed by:
Encube Ethicals, Inc.
200 Meredith Drive,
Suite 202, Durham,
NC 27713, USA


EBV3B/00

Athlete's Foot Cream
Clotrimazole Cream
USP, 1%
NET WT. 0.5 OZ (14 g)

Drug Facts	Active Ingredient Clotrimazole USP 1% Antifungal
Uses Cures 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.	
Directions Apply a thin layer of the product over affected area twice daily (morning and night), or as directed by a doctor. Separate children in the use of the product. For athlete's foot, jock itch, and ringworm: Wash affected areas and socks at least once daily. After drying, apply special attention to spaces between the toes. Wear socks and shoes that are clean and dry. For athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks. If condition does not improve, contact a doctor. This product is not effective on the scalp or nails.	
Other Information Store at room temperature 20°C to 25°C (68°F to 77°F). Before using any medication, read all label directions. Keep container closed when not in use. Important information: Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
Inactive Ingredients Benzalkonium chloride, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polyurethane 60, purified water, sodium phosphate monobasic, sorbitan monostearate	
Questions or comments? Call 1-833-285-4151	

Athlete's Foot Cream
Clotrimazole Cream USP, 1% (Antifungal)
NET WT. 1 OZ (28 g)

Drug Facts	
Active ingredient Clotrimazole, USP 1%	Purpose Antifungal
Uses ■ cures 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 foot 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.	
Drug Facts (continued)	
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°C to 25°C (68°F to 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	
Questions or comments? Call 1-833-285-4151	


Athlete's Foot Cream
 Clotrimazole Cream
 USP, 1% NET WT. 1 OZ (28 g)

EBU3A00


Manufactured by:
 Encube Ethicals Pvt. Ltd.
 Plot No. C-1, Madkaim
 Industrial Estate, Madkaim,
 Post: Marol, Ponda,
 Goa - 403 404, India.

Distributed by:
 Encube Ethicals, Inc.
 200 Meredith Drive,
 Suite 202, Durham,
 NC 27713, USA


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

NDC 21922-094-05

Mfg. Lic. No.: 361



EMBOSSED
 AREA



Athlete's Foot Cream
 ANTIFUNGAL
 Cures most athlete's foot
 Relieves itching, burning, cracking & scaling

Encube

NDC 21922-094-05

Clotrimazole Cream USP, 1% NET WT. 1 OZ (28 g)

Athlete's Foot Cream
 ANTIFUNGAL
 Cures most athlete's foot
 Relieves itching, burning, cracking & scaling

Encube

NDC 21922-094-05

Clotrimazole Cream USP, 1% NET WT. 1 OZ (28 g)

Compare to the active ingredient in Lotrimin® AF Athlete's Foot Cream*

Athlete's Foot Cream
 ANTIFUNGAL
 Cures most athlete's foot
 Relieves itching, burning, cracking & scaling

Encube

NDC 21922-094-05

Clotrimazole Cream USP, 1% NET WT. 1 OZ (28 g)

Compare to the active ingredient in Lotrimin® AF Athlete's Foot Cream*

ANTIFUNGAL
 clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21922-094
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21922-094-04	1 in 1 CARTON	03/06/2025	
1		14 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:21922-094-05	1 in 1 CARTON	03/06/2025	
2		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 Drug	M005	03/06/2025	

Labeler - Encube Ethicals Private Limited (915834105)

Establishment

Name	Address	ID/FEI	Business Operations
Encube Ethicals Private Limited		725076298	ANALYSIS(21922-094) , LABEL(21922-094) , MANUFACTURE(21922-094) , PACK(21922-094)