

CLOTRIMAZOLE CREAM, 1%- clotrimazole cream

Pharmaceutica North America, Inc

Active Ingredient

Clotrimazole USP 1%

Purpose

Antifungal

Uses

Cures athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis)

Relieves the itching, irritation, redness, scaling and discomfort which can 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 within 2 weeks (for jock itch)
- **Keep this and all drugs out of reach of children.** In case of an accidental ingestion, seek professional assistance or contact a Poison Control Center right away.

Directions

- Wash the affected area and dry thoroughly
- Apply a thin layer 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 the 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 persists longer, consult a doctor.
- This product is not effective on the scalp or nails.

Other information

- Store at controlled room temperature 15 – 30 C (50 – 86F)
- Close cap tightly after use.

Inactive Ingredients

Alcohol, Butylated hydroxytoluene, Cetostearyl alcohol, Dimethyl sulfoxide, Edetate disodium, Ethylparaben, Glycerol, Mineral oil, Mono- and di-glycerides, Petrolatum, Polyoxyethylene lauryl ether, Purified water

Product label

The product label is rectangular with a blue border. At the top left, there is a barcode. To its right, the NDC number 'NDC 45861-099-07' is printed in white on a blue background. The main title 'Clotrimazole Cream, 1%' is prominently displayed in large, bold, black font. Below the title, there is a section for 'Active ingredient' and 'Purpose'. The 'Active ingredient' section lists 'Clotrimazole USP 1% w/w'. The 'Purpose' section lists 'Antifungal'. Below these, there are sections for 'Uses', 'Warnings', 'Stop use and ask a doctor if', and 'Directions'. The 'Net Content 29gm/1.23oz' is printed at the bottom left. A decorative graphic of a circular pattern of dots is located at the bottom center of the label.

NDC 45861-099-07

Manufactured For:
Pharmaceutica North America, Inc.,
Glendale, CA 91205 Tel 888-788-6472

Clotrimazole Cream, 1%

Active ingredient
Clotrimazole USP 1% w/w

Purpose
Antifungal

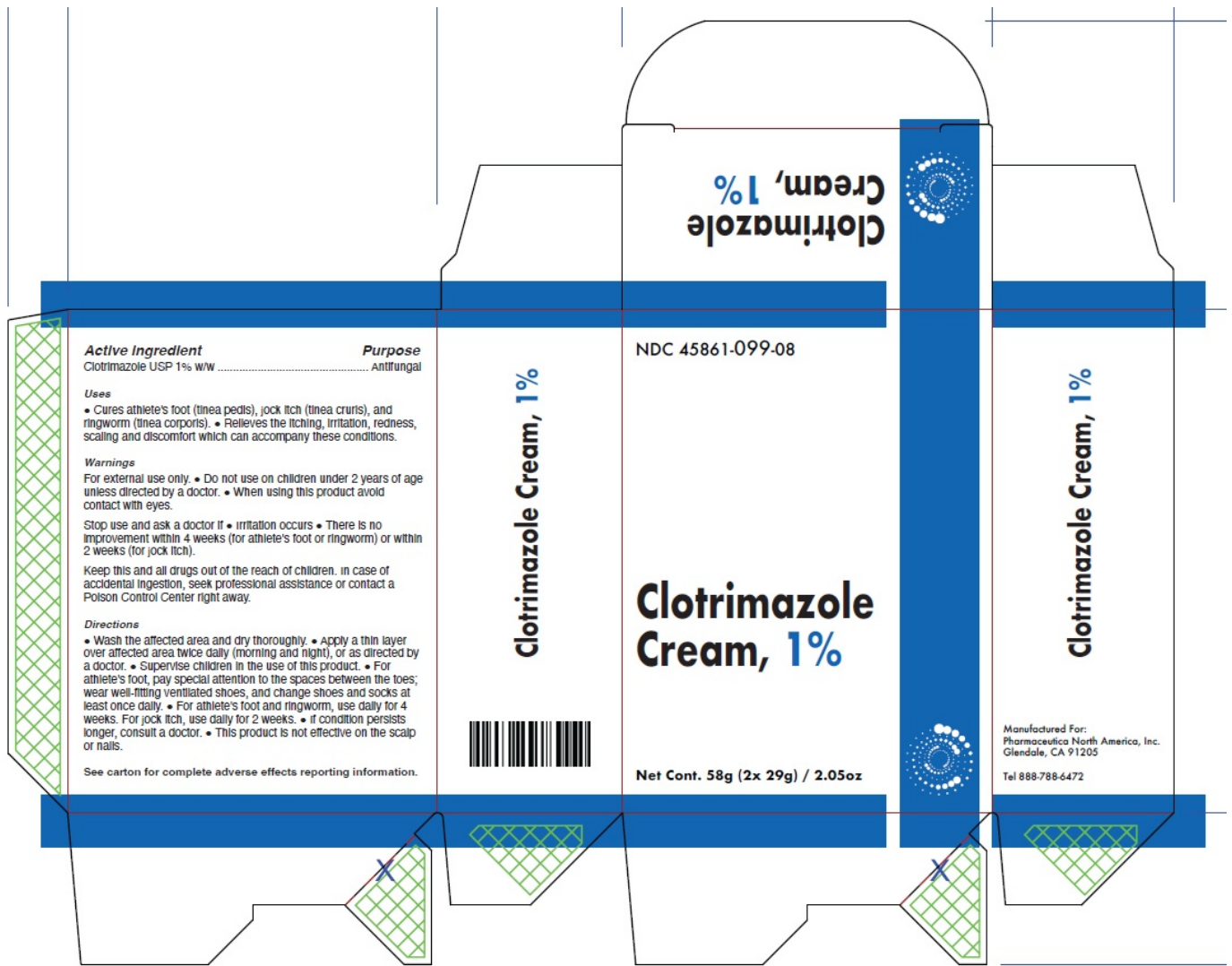
Uses • Cures athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis). • Relieves the itching, irritation, redness, scaling and discomfort which can accompany these conditions.

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 within 2 weeks (for jock itch). Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away.

Directions • Wash the affected area and dry thoroughly. • Apply a thin layer 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 the 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 persists longer, consult a doctor. • This product is not effective on the scalp or nails. See carton for complete adverse effects reporting information.

Net Content 29gm/1.23oz



CLOTRIMAZOLE CREAM, 1%

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45861-099
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALCOHOL (UNII: 3K9958V90M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERETH-31 (UNII: 11L9WC241B)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45861-099-07	29 g in 1 TUBE; Type 0: Not a Combination Product	12/10/2024	
2	NDC:45861-099-08	2 in 1 CARTON	02/07/2025	
2		58 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	12/10/2024	

Labeler - Pharmaceutica North America, Inc (962739699)

Revised: 2/2025

Pharmaceutica North America, Inc