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 athletes foot or ringworm) or within 2 weeks (for jock itch)
- **Keep this and all drugs out of reach of children**. In case of a 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 athletes' 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 athletes 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.

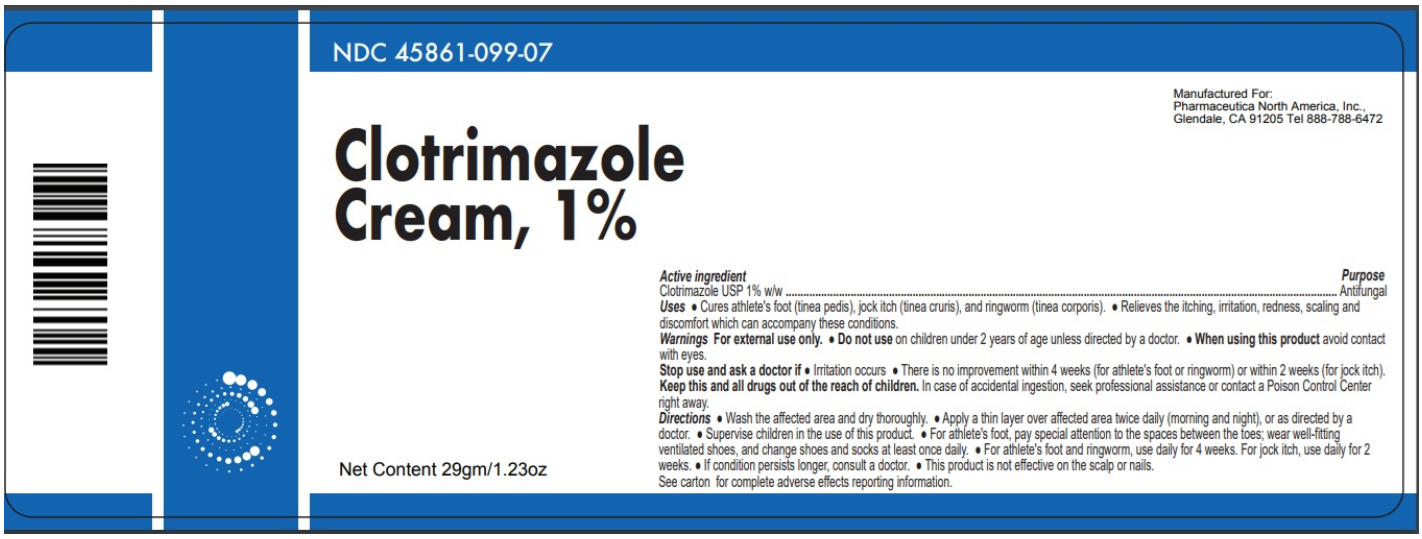
Other information

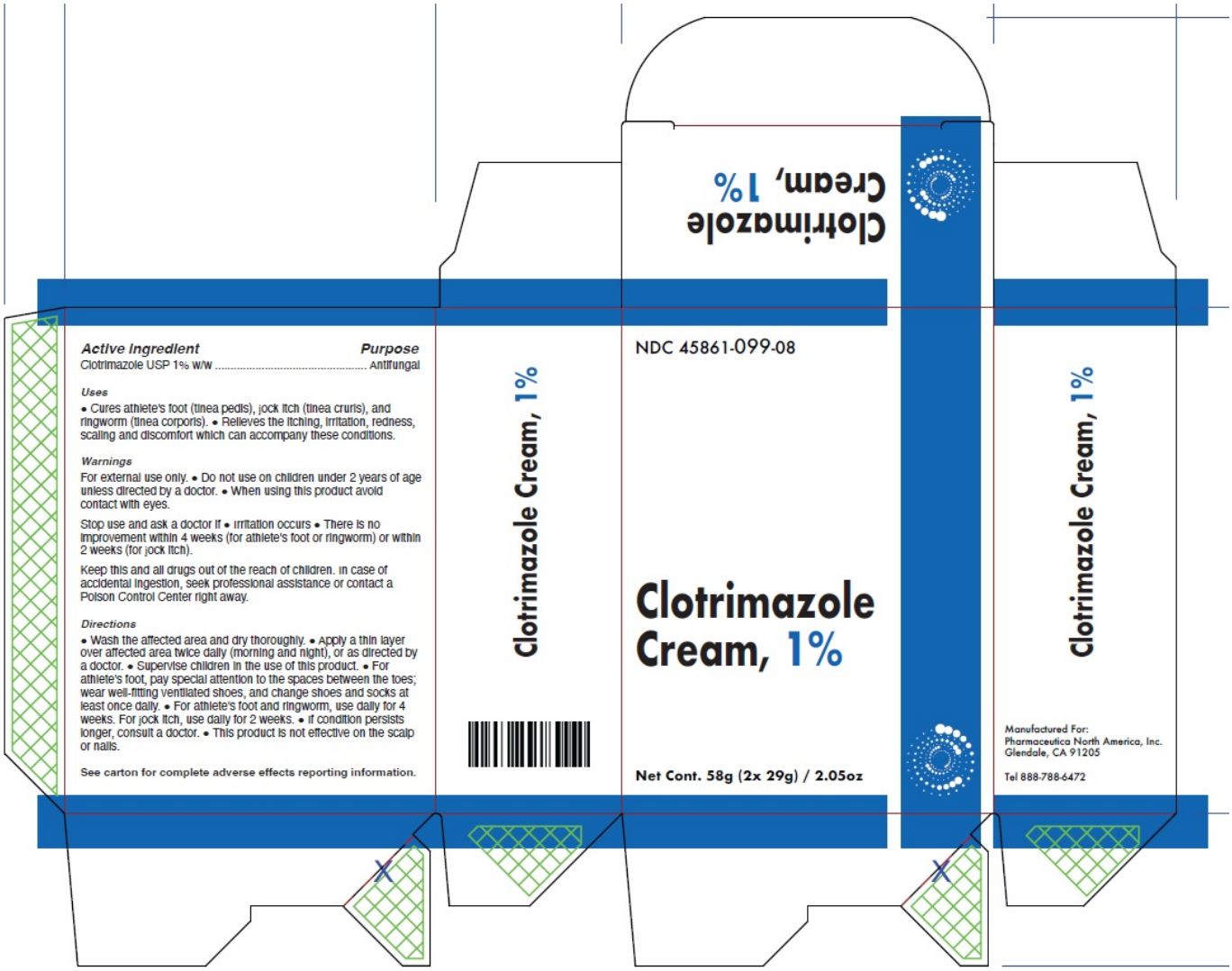
• Store at controlled room temperature 15 – 30 C (50 – 86F)
• Close cap tightly after use.

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





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