

ANTIFUNGAL CREAM - miconazole nitrate cream
Encube Ethicals Private Limited

Antifungal Cream
Miconazole Nitrate Cream,
USP 2%

ACTIVE INGREDIENT(S)

Miconazole nitrate, USP 2%

PURPOSE

Antifungal

USE(S)

- proven clinically effective in the treatment of most athlete's foot, jock itch, and ringworm
- for effective relief of itching, scaling, cracking, burning, 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

- clean 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 the spaces between the toes; wear well-filling, 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

- do not use if foil seal on tube opening is broken or missing
- to open tube: unscrew cap, lift tab, and pull to remove foil seal prior to use
- store at room temperature 15°C to 30°C (59°F to 86°F)
- before using any medication, read all label directions. Keep carton, it contains important information.

INACTIVE INGREDIENTS

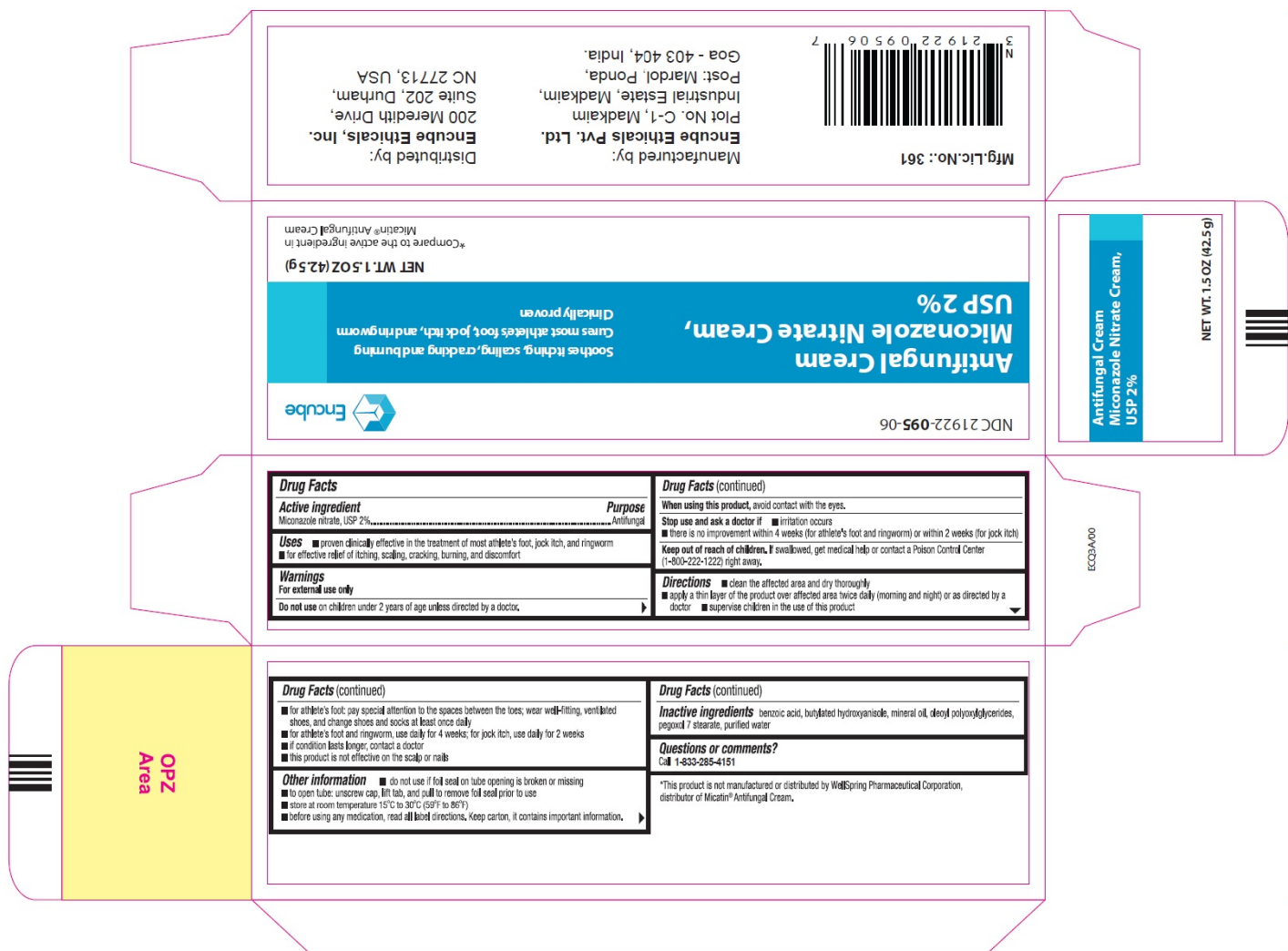
benzoic acid, butylatylated; hydroxyanisole, mineral oil, oleoyl polyoxylglycerides, pegoxol 7stearate, purified water

QUESTIONS OR COMMENTS?

Call 1-833-285-4151

PRINCIPAL DISPLAY PANEL

Antifungal Cream
Miconazole Nitrate Cream, USP 2%
NET WT. 1.5 OZ (42.5 g)



ANTIFUNGAL CREAM

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21922-095
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MINERAL OIL (UNII: T5L8T28FGP)	
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	

WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21922-095-06	1 in 1 CARTON	03/06/2025	
1		42.5 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(21922-095) , LABEL(21922-095) , MANUFACTURE(21922-095) , PACK(21922-095)

Revised: 3/2025

Encube Ethicals Private Limited