#### MICONAZOLE NITRATE 2%- miconazole nitrate cream Akron Pharma Inc.

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#### MEDPURA MICONAZOLE Nitrate 2% ANTIFUNGAL CREAM

Soothes itching, scaling, cracking and burning Cures most athlete's foot, jock itch and ringworm

# **Drug Facts**

## Active ingredient

Miconazole Nitrate, USP 2%

## Purpose

Anti-Fungal

#### Uses

- 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

# 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 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

# 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.

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

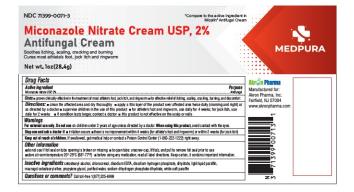
**Inactive ingredients** cetostearyl alcohol, chlorocresol, disodium EDTA, disodium hydrogen phosphate, dihydrate, light liquid paraffin,

macrogol cetostearyl ether, propylene glycol, purified water, sodium dihydrogen phosphate dihydrate, white soft paraffin

Call toll-free 1(877)225-6999 Manufactured for: Akron Pharma, Inc. Fairfield, NJ 07004











Miconazole Nitrate Cream USP, 2% 1.5oz(45g)



MICONAZOLE NITRATE 2% miconazole nitrate cream						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-0071			
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		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
CHLOROCRESOL (UNII: 36W53O7109)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)			
PARAFFINUM LIQUIDUM (UNII: T5L8T28FGP)			
CETEARETH-12 (UNII: 7V4MR24V5P)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)			
PARAFFIN (UNII: I900E3H2ZE)			

#### Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399- 0071-1	1 in 1 BOX	11/19/2024	
1		14.2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71399- 0071-3	1 in 1 BOX	11/19/2024	
2		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:71399- 0071-4	1 in 1 BOX	11/19/2024	
3		42.5 g in 1 TUBE; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M005	11/19/2024	

Labeler - Akron Pharma Inc. (067878881)

Revised: 11/2024

Akron Pharma Inc.