

**MICONAZOLE NITRATE- miconazole nitrate ointment
ALLIED TRADE LINK LLC**

Miconazole Nitrate

Uses

For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) Relieves itching, scaling, burning, discomfort and chafing associated with jock itch or itching, burning feet

Warnings For External Use Only

Do not use On children under 2 years of age unless directed by a doctor For diaper rash.

When using this product Avoid contact with the eyes

Stop use and ask a doctor if Irritation occurs There is no improvement within 2 weeks when used for the treatment of jock itch There is no

improvement within 4 weeks when used for athlete's foot and ringworm

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Do not use

Do not use On children under 2 years of age unless directed by a doctor For diaper rash.

When using this product Avoid contact with the eyes

Stop use and ask a doctor if

Stop use and ask a doctor if Irritation occurs There is no improvement within 2 weeks when used for the treatment of jock

itch There is no improvement within 4 weeks when used for athlete's foot and ringworm

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Other Information

Do not use if seal on the tube is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal See crimp of tube or carton for Lot Number and Expiry Date Preserve in well-closed containers, and store controlled room temperature

Inactive Ingredients

Inactive Ingredients Cetostearyl Alcohol, Chlorocresol, Edetate Disodium, Light Mineral Oil, Macrogol Cetostearyl Ether, Propylene Glycol, Purified Water, Sodium Phosphate Dibasic Dihydrate, Sodium Phosphate Monobasic Dihydrate, White Petrolatum

Active Ingredient

Miconazole Nitrate 2%

WARNINGS FOR EXTERNAL USE ONLY

Miconazole Nitrate 2%

For External Use Only

Do not use On children under 2 years of age unless directed by a doctor For diaper rash.

When using this product Avoid contact with the eyes

Stop use and ask a doctor if Irritation occurs There is no improvement within 2 weeks when used for the treatment of jock itch There is no

improvement within 4 weeks when used for athlete's foot and ringworm

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS AND USES

Uses

For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) Relieves itching, scaling, burning, discomfort and chafing associated with jock itch or itching, burning feet

Clean the affected area and dry thoroughly Apply a thin layer of the cream 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,

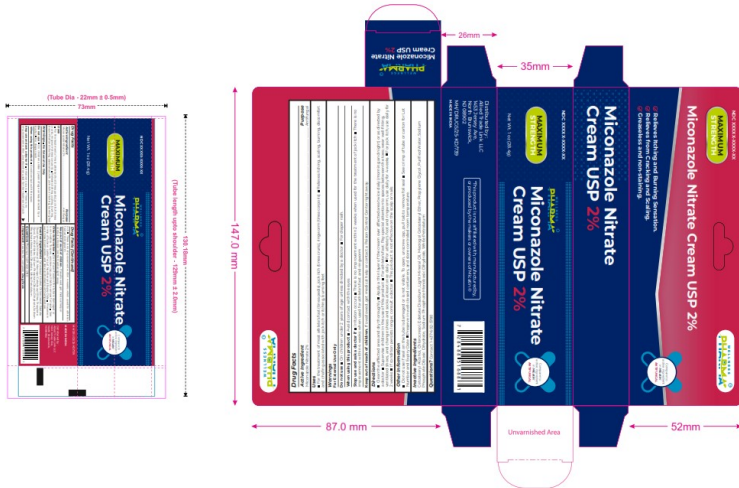
ventilated shoes, and change shoes and socks at least once daily For athlete's foot and ringworm, use daily for 4 weeks For jock itch, use daily for

2 weeks If condition persists longer, consult a doctor This product is not effective on the scalp or nails

PURPOSE

Miconazole Nitrate 2%

Antifungal



MICONAZOLE NITRATE				
miconazole nitrate ointment				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84387-003	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	MICONAZOLE NITRATE (UNII: VV4H1CYW1K) (MICONAZOLE - UNII:7NN00D755M)	MICONAZOLE NITRATE	20 mg in 1 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
	CHLOROCRESOL (UNII: 36W53O7109)			
	CETEARETH-12 (UNII: 7V4MR24V5P)			
	2-PHENYLPROPANAL PROPYLENE GLYCOL ACETAL (UNII: 1Z RR9A405A)			
	SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 94255I6E2T)			
	SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)			
	LIGHT MINERAL OIL (UNII: N6K5787QVP)			
	WATER (UNII: 059QF0K0OR)			
	WHITE PETROLATUM (UNII: B6E5W8RQJ4)			
	EDETATE DISODIUM (UNII: 7FLD91C86K)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84387-003-01	28.4 g in 1 TUBE; Type 0: Not a Combination Product	10/25/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M005	10/25/2024		

Labeler - ALLIED TRADE LINK LLC (029033682)

Registrant - ALLIED TRADE LINK LLC (029033682)

Establishment				
Name	Address	ID/FEI	Business Operations	
GOPALDAS VISRAM AND COMPANY LIMITED		858030888	manufacture(84387-003)	

Revised: 11/2024

ALLIED TRADE LINK LLC