

FUNGOID TINCTURE- miconazole nitrate tincture
Pedinol Pharmacal, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Miconazole nitrate 2% USP

Purpose

Antifungal

Uses

- cures most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- for effective relief of itchy, scaly skin between the toes

Warnings

For external use only

Flammable:

Do not use while smoking or near heat or flame.

Do not use

on children under 2 years of age unless directed by a doctor.

When using this product

- avoid contact with the eyes.
- if irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center 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 spaces between 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

- if condition persists longer, consult a doctor
- this product is not effective on scalp or nails.

Other information

- store at controlled room temperature 15-30°C (59-86°F)

Inactive ingredients

acetic acid, benzyl alcohol, isopropyl alcohol (30%), laureth-4, water

Questions or comments?

1-800-321-4576

Fungoid Tincture – 1 fl. oz. (29.57 mL) Carton

NDC 0884-0293-01

PEDiNOL®

fungoid® tincture

miconazole nitrate 2%

topical antifungal

1 fl. oz. (29.57 mL)



FUNGOID TINCTURE

miconazole nitrate tincture

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0884-0293
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4HICYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Acetic Acid (UNII: Q40Q9N063P)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Isopropyl Alcohol (UNII: ND2M416302)	
Laureth-4 (UNII: 6HQ855798J)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0884-0293-01	1 in 1 CARTON	04/11/2012	
1		29.57 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/11/2012	

Labeler - Pedinol Pharmacal, Inc. (064737125)

Establishment

Name	Address	ID/FEI	Business Operations
EMS Contract Packaging		048602791	MANUFACTURE(0884-0293)

Revised: 5/2020

Pedinol Pharmacal, Inc.