

FUNGOID TINCTURE TREATMENT KIT- miconazole nitrate
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.

Fungoid® Tincture Treatment Kit

Drug Facts

Active Ingredient

Miconazole Nitrate 2%

Purpose

Topical 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.
- do not use on children under 2 yrs unless directed by a doctor.
- avoid contact with eyes.
- if irritation occurs or if there is no improvement within four weeks, discontinue use and consult a doctor.

KEEP OUT OF REACH OF CHILDREN

If swallowed, seek medical attention immediately.

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

Recommended Storage

- store at controlled room temperature 15° - 30°C (59° - 86°F)
- Protect from freezing. If freezing occurs, warm to room temperature.

Inactive Ingredients

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

Retain product insert for full directions and warnings

Questions or comments?

1-800-PEDiNOL (733-4665) or visit www.pedinol.com

Principal Display Panel – Kit Carton

NDC 0884-5493-01

PEDiNOL™

fungoid® tincture

treatment kit

miconazole nitrate 2%

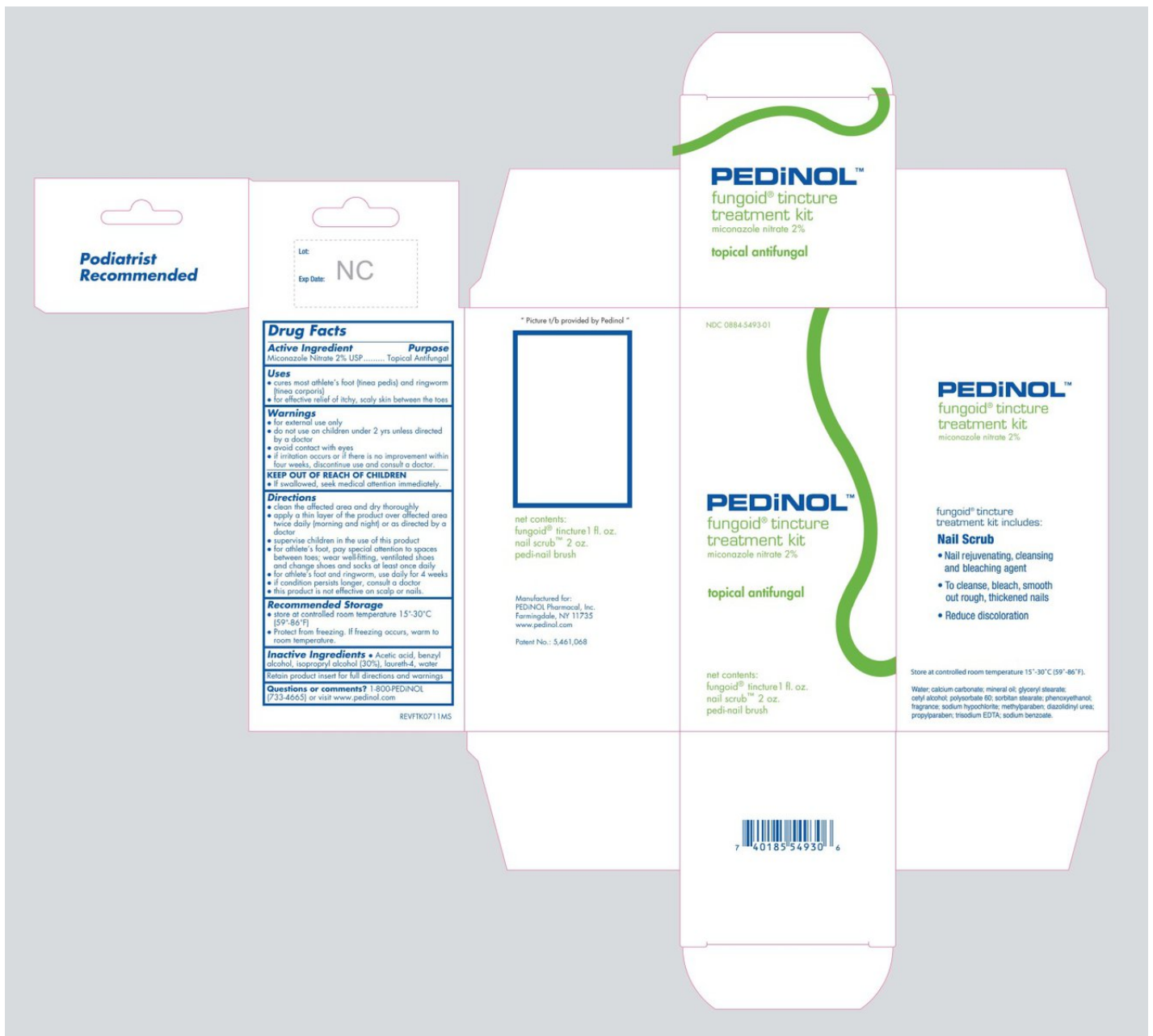
topical antifungal

net contents:

fungoid® tincture 1 fl. oz.

nail scrub™ 2 oz.

pedi-nail brush



Principal Display Panel – Nail Scrub Label

0884-4891-02

PEDiNOL™

nail scrub™

nail rejuvenating,
cleansing & bleaching
agent

net wt. 2 oz. (56.7g)

0884-4891-02

PEDINOL™ nail scrub™

nail rejuvenating,
cleansing & bleaching
agent

net wt. 2 oz. (56.7g)



Nail Scrub™ cleanses, bleaches and smooths out rough, thickened nails and reduces discoloration.

DIRECTIONS: Shake well before using. Remove cap, apply Nail Scrub to nails surface. Scrub briskly with nail brush. Wash off nail and dry.

WARNINGS: For external use only. KEEP OUT OF REACH OF CHILDREN. Consult your doctor if you have diabetes or impaired circulation prior to using. Do not use if you are sensitive to any ingredient in this product.

STORAGE: Store at controlled room temperature.

INGREDIENTS: Water; calcium carbonate; mineral oil; glyceryl stearate; cetyl alcohol; polysorbate 60; sorbitan stearate; phenoxyethanol; fragrance; sodium hypochlorite; methylparaben; diazolidinyl urea; propylparaben; trisodium EDTA; sodium benzoate.

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Manufactured for:
PEDINOL PHARMACAL INC.
Farmingdale, NY 11735



REV N80112CR

FUNGOID TINCTURE TREATMENT KIT

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0884-5493
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0884-5493-01	1 in 1 CARTON; Type 0: Not a Combination Product	01/01/1994	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	0 BOTTLE, WITH APPLICATOR	1 mL
Part 2	0 BOTTLE	1 g

Part 1 of 2

FUNGOID TINCTURE

miconazole nitrate tincture

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (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		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	01/01/1994	

Part 2 of 2

NAIL SCRUB

other manicuring preparations

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0K00R)	
INGR	CALCIUM CARBONATE (UNII: H0G9379FGK)	
INGR	MINERAL OIL (UNII: T5L8T28FGP)	

INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	SODIUM HYPOCHLORITE (UNII: DY38VHM5OD)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC10H)	
INGR	EDETATE TRISODIUM (UNII: 420IP921MB)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		56.7 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/1994	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/01/1994	

Labeler - Pedinol Pharmacal, Inc. (064737125)

Establishment

Name	Address	ID/FEI	Business Operations
EMS Contract Packaging		048602791	MANUFACTURE(0884-5493)

Revised: 12/2018

Pedinol Pharmacal, Inc.