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.

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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 or visit www.pedinol.com

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
Route of Administration: TOPICAL

Item Code (Source): NDC:0884-0293

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miconazole Nitrate (UNII: VW4HICYW1K) (Miconazole - UNII:7NNO0D7SSM)</td>
<td>Miconazole Nitrate</td>
<td>20 mg in 1 mL</td>
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</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic Acid (UNII: Q40Q9N063P)</td>
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</tr>
<tr>
<td>Benzyl Alcohol (UNII: LKG8494WBH)</td>
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<tr>
<td>Isopropyl Alcohol (UNII: ND2M416302)</td>
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<tr>
<td>Laureth-4 (UNII: 6HQ855798J)</td>
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### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:0884-0293-01</td>
<td>1 in 1 CARTON</td>
<td>01/01/1994</td>
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<tr>
<td>1</td>
<td></td>
<td>29.57 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product</td>
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### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>OTC monograph final</td>
<td>part333C</td>
<td>01/01/1994</td>
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### Labeler - Pedinol Pharmacal, Inc. (064737125)

### Establishment

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<thead>
<tr>
<th>Name</th>
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<th>ID/FEI</th>
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<td>EMS Contract Packaging</td>
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<td>048602791</td>
<td>MANUFACTURE(0884-0293)</td>
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Revised: 12/2018