Miconazole Nitrate Vaginal Cream, USP

Drug Facts

Active ingredient
Miconazole nitrate, USP 2% (100 mg in each applicator)

Purpose
Vaginal antifungal

Uses
• treats vaginal yeast infections
• relieves external itching and irritation due to a vaginal yeast infection

Warnings
For vaginal use only

Do not use
if you have never had a vaginal yeast infection diagnosed by a doctor

Ask a doctor before use if you have
• vaginal itching and discomfort for the first time
• lower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.
• vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
• been exposed to the human immunodeficiency virus (HIV) that causes AIDS

Ask a doctor or pharmacist before use if you are
taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur

When using this product
• do not use tampons, douches, spermicides or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).
• do not have vaginal intercourse
• mild increase in vaginal burning, itching or irritation may occur
• if you do not get complete relief ask a doctor before using another product.

Stop use and ask a doctor if
• symptoms do not get better in 3 days
• symptoms last more than 7 days
• you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge
If pregnant or breast-feeding, ask a health professional before use.

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

Directions
- before using this product read the enclosed consumer information leaflet for complete directions and information
- **adults and children 12 years of age and over:**
  - **applicator:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Throw applicator away after use.
  - use the same tube of cream if you have itching and irritation on the skin outside the vagina. Squeeze a small amount of cream onto your fingertip. Apply to itchy, irritated skin outside the vagina (vulva). Use 2 times daily for up to 7 days as needed.
- **children under 12 years of age: ask a doctor**

Other information
- to open tube use cap to puncture seal
- do not use if seal over tube opening has been punctured or is not visible
- do not purchase if carton is open
- store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F).

Inactive ingredients
benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxylglycerides, pegoxol 7 stearate, purified water

Questions?
1-888-838-2872 between 9 am and 5 pm ET, Monday–Friday.

Principal display panel
Compare to the active ingredient in Monistat® 7 Vaginal Cream*

7-DAY TREATMENT
1 Tube with
7 Disposable Applicators
Miconazole 7
Miconazole Nitrate Vaginal Cream, USP 2%
(miconazole nitrate 100 mg per applicator)
VAGINAL ANTIFUNGAL
7-DAY TREATMENT
Cures most vaginal yeast infections
Relieves associated external itching and irritation
RITE AID® PHARMACY
Miconazole 7
Miconazole Nitrate Vaginal Cream, USP 2% (Miconazole nitrate 100 mg per applicator)

VAGINAL ANTIFUNGAL
7-DAY TREATMENT
Cures most vaginal yeast infections
Relieves associated external itching and irritation

DISTRIBUTED BY:
RITE AID CORPORATION
CAMARILLO, CA 93010

Satisfaction Guarantee
If you are not satisfied, return it. We'll happily refund your purchase.

NET WT 1.59 OZ (45 g) TUBE
7 DAY VAGINAL CREAM (1 TUBE)
WITH 7 DISPOSABLE APPLICATORS
**MICONAZOLE 7**
miconazole nitrate cream

### Product Information

<table>
<thead>
<tr>
<th><strong>Product Type</strong></th>
<th>HUMAN OTC DRUG</th>
<th><strong>Item Code (Source)</strong></th>
<th>NDC:11822-0730</th>
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<tbody>
<tr>
<td><strong>Route of Administration</strong></td>
<td>VAGINAL</td>
<td></td>
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### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th><strong>Ingredient Name</strong></th>
<th><strong>Basis of Strength</strong></th>
<th><strong>Strength</strong></th>
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<tbody>
<tr>
<td>MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)</td>
<td>MICONAZOLE NITRATE</td>
<td>20 mg in 1 g</td>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th><strong>Ingredient Name</strong></th>
<th><strong>Strength</strong></th>
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<tbody>
<tr>
<td>BENZOIC ACID (UNII: 8SKN0B0MIM)</td>
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<tr>
<td>BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)</td>
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<tr>
<td>MINERAL OIL (UNII: T5L8T28FGP)</td>
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<tr>
<td>APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)</td>
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<tr>
<td>PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)</td>
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<td>WATER (UNII: 059QF0KOOR)</td>
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### Product Characteristics

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<tr>
<th><strong>Color</strong></th>
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<td><strong>Flavor</strong></td>
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### Packaging

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<tr>
<th>#</th>
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<th><strong>Marketing End Date</strong></th>
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<td>NDC:11822-0730-1</td>
<td>1 in 1 CARTON</td>
<td>03/01/2001</td>
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<td>1</td>
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<td>45 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product</td>
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### Marketing Information

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<tr>
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<th><strong>Application Number or Monograph Citation</strong></th>
<th><strong>Marketing Start Date</strong></th>
<th><strong>Marketing End Date</strong></th>
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Rite Aid Corporation

ANDA - ANDA074164

03/01/2001

Labeler - Rite Aid Corporation (014578892)

Revised: 11/2019

Rite Aid Corporation