MICONAZOLE NITRATE - miconazole nitrate cream
Cosette Pharmaceuticals, Inc.

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Miconazole Nitrate Vaginal Cream 2 %
7 Day Vaginal Cream

ACTIVE INGREDIENT
Miconazole nitrate 2% (100 mg in each applicator)
Miconazole nitrate 2% (as external cream)

PURPOSE
Vaginal antifungal

USES
• treats repeat vaginal yeast infections
• relieves external itching and irritation due to a repeat 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 medication warfarin, because bleeding or bruising may occur.

When using this product
• do not use tampons, douches, spermicides, or other vaginal products
• do not have vaginal intercourse
• condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs)

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.

**DOSAGE & ADMINISTRATION**
- before using this product read the enclosed consumer information leaflet for complete instructions
- adults and children 12 years of age and over:
  - **applicator**: insert one applicatorful into the vagina at bedtime for 7 nights in a row
  - **external cream**: squeeze a small amount of cream onto your fingertip. Gently apply the cream onto the itchy, irritated skin outside the vagina. Use daily for up to 7 days as needed
- children under 12 years of age: ask a doctor

**OTHER INFORMATION**
- do not use if seal over tube opening has been punctured or cannot be seen
- store at room temperature 15°-30°C (59°-86°F). Avoid heat over 30°C or 86°F.

**INACTIVE INGREDIENT**
benzoic acid, BHA, mineral oil, peglicol 5 oleate, pegoxol 7 stearate, purified water

**QUESTIONS**
1-800-922-1038

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 45 g Tube Carton**
Miconazole Nitrate Vaginal Cream 2%
Vaginal Antifungal
7 Day Vaginal Cream
Relieves external vulvar itching and irritation associated with a yeast infection
CURES MOST VAGINAL YEAST INFECTIONS
NET WT 1.59 OZ (45g)
### MICONAZOLE NITRATE

**miconazole nitrate cream**

#### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:0713-0252</th>
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<tbody>
<tr>
<td>Route of Administration</td>
<td>VAGINAL</td>
<td></td>
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#### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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</thead>
<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>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>BENZOIC ACID (UNII: 8SKN0B0MIM)</td>
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</table>
### BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)

**MINERAL OIL** (UNII: T5L8T28FGP)

**PEG-5 OLEATE** (UNII: 0240V77G50)

**PEGOMOL 7 STEARATE** (UNII: 3EW5AXE5X5)

**WATER** (UNII: 059QF0KO0R)

### 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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<td>45 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product</td>
<td>02/22/1996</td>
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### Marketing Information

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<th>Application Number or Monograph Citation</th>
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<th>Marketing End Date</th>
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<tr>
<td>ANDA</td>
<td>ANDA074366</td>
<td>02/22/1996</td>
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**Labeler** - Cosette Pharmaceuticals, Inc. (116918230)

**Registrant** - Cosette Pharmaceuticals, Inc. (116918230)

### Establishment

<table>
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<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<td>Cosette Pharmaceuticals, Inc.</td>
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<td>116918230</td>
<td>analysis(0713-0252) , manufacture(0713-0252) , label(0713-0252) , pack(0713-0252)</td>
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Revised: 8/2019