

**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)

**Drug Facts (continued)**

**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 2 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 7 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 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

**Drug Facts (continued)**

**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 ingredients** benzoic acid, B-K, mineral oil, polycol 5 oleate, polycol 7 stearate, purified water

**Questions?** 1-800-022-1038

Manufactured by: G&W Laboratories, Inc.  
111 Coolidge Street, South Plainfield, NJ 07080  
Visit our website @ [www.gwflabs.com](http://www.gwflabs.com)



**7 Day Vaginal Cream**

**CURES MOST VAGINAL YEAST INFECTIONS**

**Miconazole Nitrate**  
Vaginal Cream 2%  
Vaginal Antifungal

**NET WT**  
**1.59 OZ (45 g)**

Relieves external vulvar itching and irritation associated with a yeast infection

**Drug Facts**

**Active ingredient**

Miconazole nitrate 2% (100 mg in each applicator).....Vaginal antifungal  
Miconazole nitrate 2% (as external cream).....Vaginal antifungal

**Purpose**

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

80% UPC  
do not print keyline  
N3-0713-0252-37-9

**MICONAZOLE NITRATE**

miconazole nitrate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0713-0252
<b>Route of Administration</b>	VAGINAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	

<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PEG-5 OLEATE</b> (UNII: 0240V77G50)	
<b>PEGOXOL 7 STEARATE</b> (UNII: 3EW5AXE5X5)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0252-37	45 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	02/22/1996	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074366	02/22/1996	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals, Inc.		116918230	analysis(0713-0252) , manufacture(0713-0252) , label(0713-0252) , pack(0713-0252)

Revised: 8/2019

Cosette Pharmaceuticals, Inc.