

**MICONAZOLE 7- miconazole nitrate cream**  
**CVS Pharmacy**

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**Miconazole 7**

***Drug Facts***

**Active ingredient**

Miconazole nitrate USP 2%

**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 (1-800-222-1222) 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:
  - **applicators:** 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 the cream onto the itchy, irritated skin outside the vagina. Use 2 times 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
- do not purchase if carton is open
- store at 20° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

### **Inactive ingredients**

benzoic acid (0.20%) as a preservative, butylated hydroxytoluene, mineral oil, oleoyl polyoxyglyceride, PEG-6-32 stearate/glycol stearate, and purified water.

### **Questions?**

call **1-866-923-4914**

**Distributed by: CVS Pharmacy, Inc.**

One CVS Drive, Woonsocket, RI 02895

### **PRINCIPAL DISPLAY PANEL - 45 g Tube Carton**

CVSHealth™

Compare to the active ingredient in Monistat® 7 Vaginal Cream\*

7-Day Treatment

Miconazole 7

MICONAZOLE NITRATE VAGINAL  
CREAM USP (2%)

Vaginal antifungal

NET WT 1.5 OZ (45 g) TUBE + 7 DISPOSABLE APPLICATORS

CVS Health.

### 7-Day Treatment

- Cures most vaginal yeast infections
- Relieves associated external itching & irritation

7 Disposable applicators



1 Tube of cream



**TAMPER EVIDENT:**  
DO NOT USE IF  
THE SEAL ON THE  
TUBE IS PUNCTURED  
OR NOT VISIBLE

5193297  
0920  
33

CVS Health.

Compare to the active ingredient in Monistat® 7 Vaginal Cream\*

7-Day Treatment

# Miconazole 7

## MICONAZOLE NITRATE VAGINAL CREAM USP (2%)

### Vaginal antifungal



NET WT 1.5 OZ (45 g) TUBE + 7 DISPOSABLE APPLICATORS

**Miconazole 7**  
MICONAZOLE NITRATE VAGINAL  
CREAM USP (2%)  
Vaginal antifungal

NET WT 1.5 OZ (45 g) TUBE

CVS Health.

NO VARNISH/NO AQ  
NO COPY / NO COLOR  
THIS FLAP FOR LOT #  
AND EXP DATE PRINT

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**CVS Quality**  
Money Back Guarantee

T241  
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ENG19-106

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**Drug Facts**

**Active ingredient**  
Miconazole nitrate USP 2%,  
vaginal antifungal

**Purpose**  
• you get a rash or itches, abdominal pain, fever, chills, nausea, vomiting,  
or food-craving vaginal discharge  
• you get a rash or itches, abdominal pain, fever, chills, nausea, vomiting,  
or food-craving vaginal discharge

**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.

**Directions**  
• before using this product read the enclosed consumer information booklet for complete directions and information  
• adults and children 12 years of age and over:  
• applicators: insert 1 applicator into the vagina at bedtime for 7 nights in a row. Those applicators 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 the cream onto the itchy, irritated skin outside the vagina. Use 2 times 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  
• do not puncture 6 tubes in open  
• see carton for tube opening instructions  
• use caution or take steps for number and expiration date

**Inactive ingredients**  
benzoic acid (0.20%), benzalkonium chloride, butylated hydroxytoluene, mineral oil, olefin polypropylene, PEG-6-20 stearyl glycol stearate, and purified water

**Questions?** call 1-855-823-8914

**Stop use and ask a doctor if**  
• symptoms do not get better in 3 days • symptoms last more than 7 days

NO VARNISH/NO AQ  
NO COPY / NO COLOR

NO VARNISH/NO AQ  
NO COPY / NO COLOR

# MICONAZOLE 7

miconazole nitrate cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-988
<b>Route of Administration</b>	VAGINAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Miconazole Nitrate</b> (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	20 mg in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Butylated Hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>Mineral Oil</b> (UNII: T5L8T28FGP)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Benzoic Acid</b> (UNII: 8SKNOB0MIM)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-988-07	1 in 1 CARTON	12/15/2016	
1		45 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074444	01/13/1997	

**Labeler** - CVS Pharmacy (062312574)