

**MICONAZOLE 7- miconazole nitrate cream  
QUALITY CHOICE (Chain Drug Marketing Association)**

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**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 (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:**
  - **applicator:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Wash applicator 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: unscrew cap, lift tab, and pull to remove foil seal prior to use
- do not use if foil seal on tube opening is broken or missing
- do not purchase if carton is open
- store at room temperature 20°-25°C (68°-77°F)
- before using any medication, read all label directions. Keep carton, it contains important information.

**Inactive ingredients**

benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxyglycerides, pegoxol 7 stearate, purified water

**Questions?**

Call **1-800-935-2362** Monday-Friday 9AM-5PM EST

**Principal display panel**

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

Miconazole 7

Miconazole Nitrate Vaginal Cream USP, 2%

Vaginal Antifungal

(Miconazole Nitrate 100 mg per applicator)

Cures Most Vaginal Yeast Infections and Relieves

Associated External Itching and Irritation

OZ NET WT (g) Tube Vaginal Cream with Reusable Applicator

\*This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat®.

Distributed by CDMA, Inc.

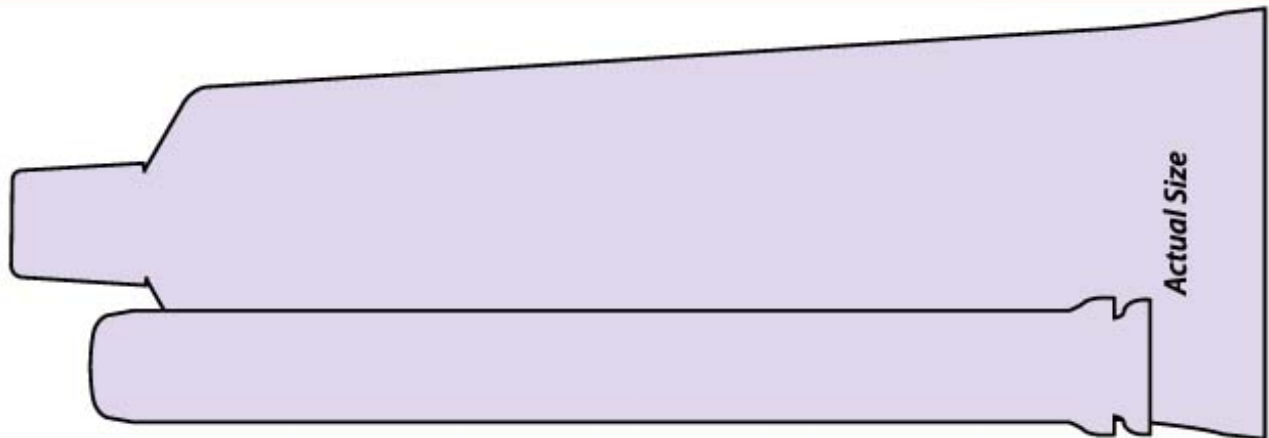
Novi, MI 48375

[www.qualitychoice.com](http://www.qualitychoice.com)

**Package label**

<b>Drug Facts</b> (continued)
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.
<b>Directions</b> ■ Before using this product read the enclosed consumer information leaflet for complete directions and information <b>adults and children 12 years of age and over:</b> ■ applicator: insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Wash applicator 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. <b>children under 12 years of age: ask a doctor</b>
<b>Other information</b> ■ Do not use if foil seal on tube opening is broken or missing ■ do not purchase if carton is open ■ store at room temperature 20°-25°C (68°-77°F) ■ before using any medication, read all label directions. Keep carton. It contains important information.
<b>Inactive ingredients</b> benzalkonium chloride, butylated hydroxytoluene, mineral oil, polyethylene glycol 7 stearate, purified water
<b>Questions?</b> Call 1-800-935-2362 Monday-Friday 9AM-5PM EST
<small>*This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat®.</small>

<b>Drug Facts</b>
<b>Active ingredient</b> Miconazole Nitrate USP, 2% (100 mg in each applicator).....Vaginal antifungal
<b>Uses</b> ■ treats vaginal yeast infections ■ relieves external itching and irritation due to a vaginal yeast infection
<b>Warnings</b> For vaginal use only
<b>Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.</b> ■ 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 recur (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 <b>Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur.</b>
<b>When using this product</b> ■ 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
<b>Stop use and ask a doctor if</b> ■ 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



NDC 63868-198-45



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

# Miconazole 7

Miconazole Nitrate Vaginal Cream USP, 2%

**Vaginal Antifungal**

(Miconazole Nitrate 100 mg per applicator)

Cures Most Vaginal Yeast Infections and Relieves Associated External Itching and Irritation



1.59 OZ NET WT (45 g) Tube

7 Day Vaginal Cream (1 Tube) with 1 Reusable Applicator



Distributed by CDMA, Inc.  
 Novi, MI 48375  
 www.qualitychoice.com  
 Questions: 800-935-2362

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PLD-C655C FC008229



Code: GO/DRUGS/361 AAL3A/04

## QUALITY CHOICE Vaginal Antifungal Cream

### MICONAZOLE 7

miconazole nitrate cream

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-198
<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 1 g

#### Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>APRICOT KERNEL OIL PEG-6 ESTERS</b> (UNII: DRG3KJZ1TJ)	
<b>PEGOXOL 7 STEARATE</b> (UNII: 3EW5AXE5X5)	
<b>WATER</b> (UNII: 059QF0KO0R)	

#### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-198-45	1 in 1 CARTON	07/01/2010	
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	ANDA074164	07/01/2010	

**Labeler** - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 9/2022

QUALITY CHOICE (Chain Drug Marketing Association)