

**MICONAZOLE 7- miconazole nitrate cream  
Cardinal Health (Leader) 49781**

-----  
**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. 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 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 polyoxyglycerides, pegoxol 7 stearate, purified water

**Questions?**

**1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.**

**Principal display panel**

**NDC 49781-064-75**

LEADER®

Compare to Monistat® 7  
active ingredient\*

Miconazole 7

Miconazole Nitrate Vaginal Cream, USP 2%

VAGINAL ANTIFUNGAL

(Miconazole Nitrate 100 mg per applicator)

Cures most vaginal yeast infections

Relieves associated external itching and irritation

SATISFACTION GUARANTEED

7 DAY VAGINAL CREAM (1 TUBE)

WITH 1 REUSABLE APPLICATOR

NET WT. 1.59 OZ (45 g) Tube

**Drug Facts**

**Active Ingredient**  
Miconazole nitrate, USP 2% (100 mg in each applicator) ..... 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

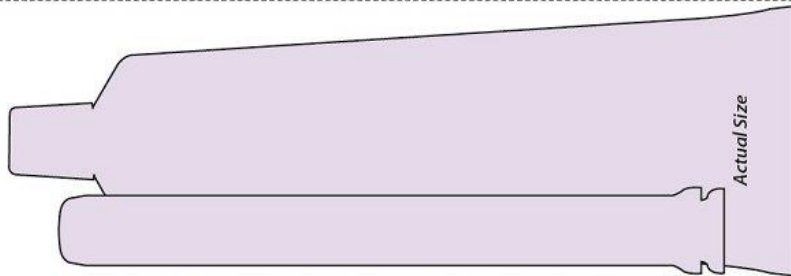
**Ask a doctor or pharmacist before use if you are taking the prescription medicine warfarin, because bleeding or bruising may occur**

**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).  
• mild increase in vaginal burning, itching or irritation may occur.

**Stop use and ask a doctor if**  
• symptoms do not get better in 3 days  
• you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge

**If you do not get complete relief ask a doctor before using another product.**

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



NDC 49781-064-75

**LEADER®**

**Miconazole 7**  
Miconazole Nitrate Vaginal Cream, USP 2%  
**VAGINAL ANTIFUNGAL**  
(Miconazole Nitrate 100 mg per applicator)

**Compare to Monistat® 7 active ingredient!**

**Cures most vaginal yeast infections**  
**Relieves associated external itching and irritation**

**7 DAY VAGINAL CREAM (1 TUBE) WITH 1 REUSABLE APPLICATOR**      NET WT 1.59 OZ (45 g) Tube

**SATISFACTION GUARANTEED**

**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:  
• use the same tube of cream if you have itching and irritation on the skin outside the vagina. Squeeze a small amount of applicator insert 1 applicator into the vagina at bedtime for 7 nights in a row. Wash applicator after use.  
• cream only your fingers. 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 hydroxytoluene, mineral oil, oleoyl polyoxyglycerides, polyoxyl 7 stearate, purified water.

**Questions?** 1-800-432-6334 between 9 am and 4 pm EST, Monday-Friday.

**Drug Facts** (continued)

**8** 0 9626295112549

www.leadertd.com  
1-800-200-6313  
REV. 3/17  
CIN 4935599  
DUBLIN, OHIO 43017  
DISTRIBUTED BY CARDINAL HEALTH  
MADE IN INDIA. CODE: GODHUGS/361  
0730516 R0317 MAJ2A1  
Manufactured by or produced by the makers or owners of Miconstat®.

This product is not affiliated with.

# MICONAZOLE 7

miconazole nitrate cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49781-064
<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:49781-064-75	1 in 1 CARTON	05/31/2014	
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	05/31/2014	

**Labeler** - Cardinal Health (Leader) 49781 (097537435)

Revised: 10/2022

Cardinal Health (Leader) 49781