

**MICONAZOLE 7- miconazole nitrate cream**  
**P & L Development, LLC**

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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° to 25°C (68° to 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 polyoxylglycerides, pegoxol 7 stearate, purified water

## **Questions?**

Call **1-877-753-3935** 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%

(miconazole nitrate 100 mg per applicator

vaginal antifungal

- cures most vaginal yeast infections
- relieves associated external itching and irritation

net wt. oz (g) tube

7 day vaginal cream (1 tube)

+ 1 reusable applicator

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

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

## **Package label**

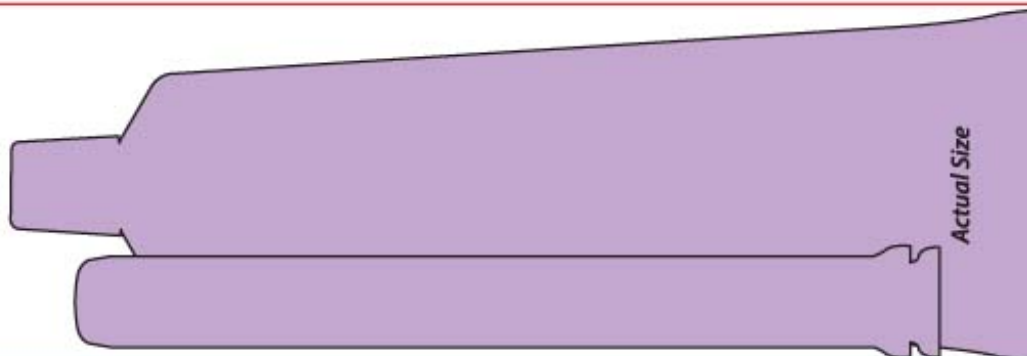


7 day vaginal cream (1 tube)  
with 1 reusable applicator

# miconazole 7

miconazole nitrate vaginal cream,  
USP 2%  
(miconazole nitrate 100 mg per applicator)

vaginal antifungal



- 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

Compare to the active ingredient in  
**Monistat® 7 Vaginal Cream\***  
NDC 59726-988-01

# miconazole 7

miconazole nitrate vaginal cream,  
USP 2%  
(miconazole nitrate 100 mg per applicator)

vaginal antifungal

# miconazole 7

miconazole nitrate vaginal cream,  
USP 2%  
(miconazole nitrate 100 mg per applicator)

vaginal antifungal

3 59726 98811 7



PLD-0655C F0000356

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cleary polypyrrolidone, povidone 7 sterile, purified water

Codex: 80/0808/361 PMSA01

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P.L. Developments  
200 Hicks Street  
Westbury, NY 11590



■ 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  
■ 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  
Stop use and ask a doctor if:  
■ symptoms do not get better in 3 days  
■ symptoms last more than 7 days  
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foul-smelling vaginal discharge

<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>	
<b>Ask a doctor before use if you have</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 (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).	
<b>Inactive ingredients</b>	
benzoic acid, butylated hydroxyanisole, mineral oil, important information.	
<b>Other information</b>	
■ 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)	
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<b>Drug Facts (continued)</b>	
<b>Directions</b>	
■ 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 applicator 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	

READYinCASE Vaginal Antifungal

MICONAZOLE 7

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-988
Route of Administration	VAGINAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M)		MICONAZOLE NITRATE	20 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)			
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)			
MINERAL OIL (UNII: T5L8T28FGP)			
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)			
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)			
WATER (UNII: 059QF0KO0R)			
Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-988-01	1 in 1 CARTON	05/28/2021	
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	05/28/2021	

**Labeler** - P & L Development, LLC (800014821)

Revised: 11/2022

P &amp; L Development, LLC