

**MICONAZOLE 7- miconazole nitrate cream**  
**H2-Pharma, LLC**

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**Miconazole 7**

***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) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°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 **1-877-753-3935** Monday-Friday 9AM-5PM EST

Distributed by: **H2-Pharma, LLC**  
Montgomery, AL 36117

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

NDC 61269-730-63

\*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. 1.59 oz (45 g) Tube

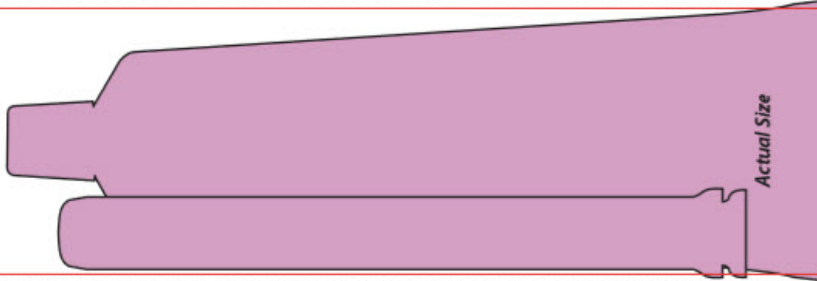
7 day vaginal cream (1 tube) with 1 reusable applicator

H<sup>2</sup>pharma

NDC 61269-730-63  
\*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



22 mm

22 mm

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NO  
VARNISH

EMBOSSING  
AREA

# Miconazole 7

## Miconazole Nitrate Vaginal Cream, USP 2% (Miconazole Nitrate 100 mg per applicator) Vaginal Antifungal

30 mm

30 mm

Distributed by: H2-Pharma, LLC  
Montgomery, AL 36117  
www.h2-pharma.com  
Call: 601/885/7011 PMS3000



NO  
VARNISH

NO  
VARNISH

**Drug Facts** (continued)

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

**Purpose** Vaginal antifungal

**Uses** Treats vaginal yeast infections

**Warnings** For vaginal use only

- Do not use if you have ever had a vaginal yeast infection diagnosed by a doctor.
- Ask a doctor before use if you have:
  - been exposed to the human immunodeficiency virus (HIV) that causes AIDS
  - diabetes or a weakened immune system
  - pregnant or have a serious underlying medical condition for the last 2 months
- Have abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or loss of appetite during and after use for the first time
- Ask a doctor before use if you have:
  - had smelly vaginal discharge; you may have a more serious condition
  - had yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or sexually transmitted diseases (STDs)
- 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
  - add moisture to vaginal opening, 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 5 days
  - symptoms last more than 7 days
  - you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge

**Directions** Before using the 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
  - each 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 (what) 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 lid seal on the opening is broken or missing
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- do not puncture if carton is open
- store at room temperature 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature] occasions permitted to 15°-30°C (59°-86°F)
- before using any medication, read all label directions. Keep carton. It contains important information.

**Inactive ingredients** Isotonic salt, purified hydroxyethylcellulose, mineral oil, methylparaben, polypropylene glycol 7 stearate, purified water

**Questions?** Call 1-877-733-3935 Monday-Friday 9AM-5PM EST

**Drug Facts** (continued)

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

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- children under 12 years of age: ask a doctor

**Other information**

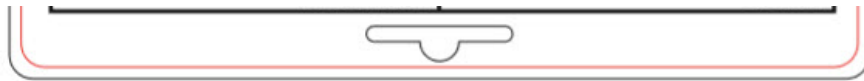
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Miconazole Nitrate  
Vaginal Cream, USP 2%  
(Miconazole Nitrate 100 mg per applicator)  
Vaginal Antifungal



## MICONAZOLE 7

miconazole nitrate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61269-730
<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:61269-730-63	1 in 1 CARTON	03/15/2021	
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	03/15/2021	

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**Labeler** - H2-Pharma, LLC (028473634)

Revised: 1/2023

H2-Pharma, LLC