

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

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**Miconazole 7**

***Drug Facts***

**Active ingredient (in each vaginal suppository)**

Miconazole nitrate, USP 100 mg

**Purpose**

Vaginal antifungal

**Use**

- treats vaginal yeast infections

**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
- vaginal yeast infections often (such as once a month or 3 in 6 months).  
**You may have a more serious condition. You could be pregnant or have a medical condition, such as diabetes or a weakened immune system.**
- lower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge
- 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
- do not use condoms or diaphragms. They may be damaged by this product and not prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse (sex)
- mild increase in vaginal burning, itching or irritation may occur

**Stop use and ask a doctor if**

- side effects occur
- symptoms do not get better after 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 instructions and information
- adults and children 12 years of age and over: insert 1 suppository into the vagina at bedtime for 7 nights in a row. Wash applicator after use.
- children under 12 years: ask a doctor

### **Other information**

- do not purchase if carton is open
- each suppository is individually wrapped. Do not use if wrapper is missing or damaged.
- store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F)

### **Inactive ingredient**

hydrogenated vegetable oil

### **Questions?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

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

### **PRINCIPAL DISPLAY PANEL - 100 mg Suppository Box**

NDC 61269-736-07

\*Compare to the active ingredient in  
Monistat® 7

Miconazole 7

Miconazole nitrate  
Vaginal suppositories, USP 100 mg  
Vaginal antifungal

Cures most vaginal yeast infections

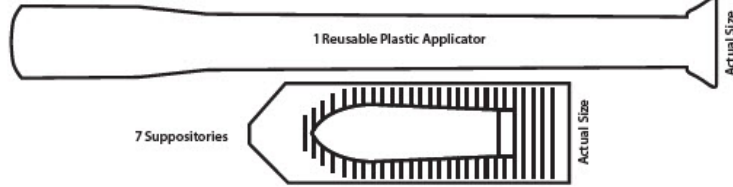
7 vaginal suppositories with 1 reusable plastic applicator

H<sup>2</sup> pharma

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Lot/Exp Print Area

Distributed by: H2-Pharma, LLC  
Montgomery, AL 36117  
www.h2-pharma.com

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### Drug Facts

**Active Ingredient**  
(in each vaginal suppository)  
Miconazole nitrate, USP 100 mg  
Vaginal antifungal

**Use**  
Treats vaginal yeast infections

**Warnings**  
For vaginal use only  
Do not use if you have never had a vaginal yeast infection diagnosis by a doctor.

Ask a doctor before use if you have:  
■ vaginal yeast infections often (such as once a month or 3 in 6 months). You may have a more serious condition. You could be pregnant or have a medical condition, such as diabetes or a weakened immune system.  
■ lower abdominal pain, or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge  
■ 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 and do not have vaginal intercourse (sex).  
■ mild increase in vaginal burning, itching or irritation may occur.

### Drug Facts (continue)

**Purpose**  
Stop use and ask a doctor if:  
■ side effects occur  
■ symptoms do not get better after 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 Poison Control Center (1-800-222-1222) right away.

**Directions**  
■ before using the product read the enclosed consumer information leaflet for complete instructions and insertion  
■ adults and children 12 years of age and over: insert 1 suppository into the vagina at bedtime for 7 nights in a row. Wash applicator after use.  
■ children under 12 years: ask a doctor.  
**Other Information**  
■ do not place in contact with open wounds or damaged skin.  
■ each suppository is individually wrapped. Do not use if wrapper is torn, damaged, or discolored.  
■ store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F).

**Inactive ingredient**  
hydrogenated vegetable oil  
**Questions?** Call 1-877-736-2323 Monday-Friday 9AM-5PM EST  
\*This product is not affiliated with, manufactured by, or produced by the makers of Monistat® 7.



## MICONAZOLE 7

miconazole nitrate suppository

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61269-736
<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	100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>HYDROGENATED PALM KERNEL OIL</b> (UNII: FM8D1RE2VP)	
<b>PALM KERNEL OIL</b> (UNII: B0S90M0233)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>	OVAL	<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:61269-736-07	7 in 1 BOX; Type 0: Not a Combination Product	05/24/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA073507	05/24/2021	

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

