

**MICONAZOLE 3 COMBINATION PACK- miconazole nitrate**  
**Chain Drug Consortium, LLC**

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**Miconazole 3 Combination Pack**

***Drug Facts***

***Active ingredients***

Miconazole nitrate, USP 200 mg (in each suppository)  
Miconazole nitrate, USP 2% (external cream)

***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 and 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.

**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 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:**
  - **suppositories:** insert 1 suppository into the vagina at bedtime for 3 nights in a row. Throw applicator away after use.
  - **external cream:** Use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Apply the cream onto the itchy, irritated skin outside the vagina. Use 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 suppository wrapper is missing or damaged (each suppository is individually wrapped)
- 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**

- suppository: hydrogenated vegetable oil
- external cream: benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxyglycerides, 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® 3\*

Miconazole 3

Combination Pack

Vaginal Antifungal

Miconazole Nitrate Vaginal Suppositories , USP 200 mg

and Miconazole Nitrate Vaginal Cream USP 2%

Cures most vaginal yeast infections and relieves associated external itching and irritation

3 Day Treatment

3 Miconazole Nitrate Vaginal Suppositories, USP 200 mg plus

1 tube Miconazole Nitrate Vaginal Cream, USP 2%

\*this product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat®3.

Net Wt OZ (g)

Distributed By:

Pharmacy Value Alliance, LLC

407 East Lancaster Avenue, Wayne, PA 19087

**Package label**

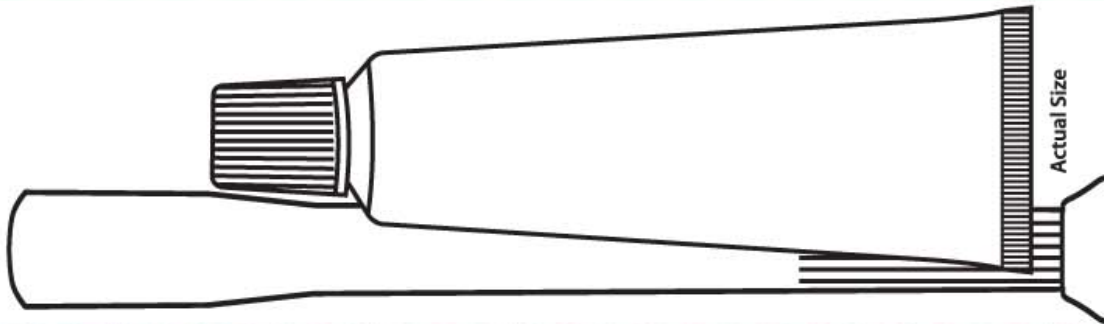


COMPARE TO THE ACTIVE INGREDIENT IN MONISTAT® 3\*

# Miconazole 3 Combination Pack

## 3 Day Treatment

3 Vaginal Suppositories with Disposable Applicators plus External Cream for Itch Relief



COMPARE TO THE ACTIVE INGREDIENT IN MONISTAT® 3\*

Cures most vaginal yeast infections and relieves associated external itching and irritation

# Miconazole 3 Combination Pack

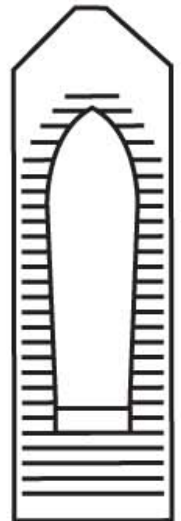
## Vaginal Antifungal

Miconazole Nitrate Vaginal Suppositories, USP 200 mg and Miconazole Nitrate Vaginal Cream, USP 2%

3 Miconazole Nitrate Vaginal Suppositories, USP 200 mg plus  
1 tube of Miconazole Nitrate Vaginal Cream, USP 2% - Net Wt 0.32 oz (9 g)



3 Suppositories



Actual Size

Distributed By:  
Pharmacy Value Alliance, LLC  
407 East Lancaster Avenue,  
Wayne, PA 19087



If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

PLD-B672A FC007133 VC710322



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<p><b>Drug Facts</b></p> <p><b>Active ingredients</b> Miconazole nitrate, USP 2% (external cream)..... Vaginal antifungal Purpose</p>	<p><b>Uses</b> ■ treats vaginal yeast infections ■ relieves external itching and irritation due to a vaginal yeast infection</p>
<p><b>Warnings</b> For vaginal use only</p> <p>Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> <li>■ vaginal itching and discomfort for the first time</li> <li>■ lower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.</li> <li>■ 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.</li> <li>■ been exposed to the human immunodeficiency virus (HIV) that causes AIDS</li> </ul> <p>Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ 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).</li> <li>■ do not have vaginal intercourse</li> <li>■ mild increase in vaginal burning, itching or irritation may occur</li> </ul> <p><b>Stop use and ask a doctor if</b> ■ symptoms do not get better in 3 days ■ symptoms last more than 7 days</p> <ul style="list-style-type: none"> <li>■ you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge</li> </ul> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p>	
<p><b>Directions</b> ■ before using this product read the enclosed consumer information leaflet for complete directions and information</p> <p>■ adults and children 12 years of age and over: ■ suppositories: insert 1 suppository into the vagina at bedtime for 3 nights in a row. Throw applicator away after use.</p> <p>■ external cream: use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Apply to itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days, as needed.</p> <p>■ children under 12 years of age: ask a doctor</p>	<p><b>Other information</b> ■ do not use if suppository wrapper is missing or damaged (each suppository is individually wrapped)</p> <ul style="list-style-type: none"> <li>■ do not use if seal over tube opening has been punctured or is not visible</li> <li>■ do not purchase if carton is open</li> <li>■ store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F)</li> </ul> <p><b>Inactive ingredients</b> suppository: hydrogenated vegetable oil external cream: benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxyglycerides, pegaxol 7 stearate, purified water</p>

**PREMIER VALUE Miconazole 3 Combination pack Vaginal Antifungal**

**MICONAZOLE 3 COMBINATION PACK**

miconazole nitrate kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-731
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-731-04	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	09/11/2003	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	3
Part 2	1 TUBE	9 g

**Part 1 of 2**

## MICONAZOLE 3

miconazole nitrate suppository

### Product Information

Route of Administration VAGINAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	200 mg

### Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	09/11/2003	

## Part 2 of 2

## MICONAZOLE 3

miconazole nitrate cream

### Product Information

Route of Administration VAGINAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	10 mg in 0.5 g

### Inactive Ingredients

Ingredient Name	Strength
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<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: 059QF0K00R)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		9 g in 1 TUBE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	09/11/2003	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	09/11/2003	

**Labeler** - Chain Drug Consortium, LLC (101668460)