

**MICONAZOLE 3 COMBINATION PACK- miconazole nitrate  
EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC)**

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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

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

**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:**
  - **suppositories:** insert 1 suppository into the vagina at bedtime for 3 nights in a row. Wash applicator away after use.
  - **external cream:** Use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Gently 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 polyoxylglycerides, pegoxol 7 stearate, purified water

***Questions?***

**1-888-287-1915**

## **Principal Display Panel**

Compare to Monistat® 3 active ingredient\*

3 Day Treatment

Miconazole

## **Combination Pack**

### **Vaginal antifungal**

Miconazole nitrate vaginal suppositories, USP 200 mg  
and Miconazole nitrate vaginal cream, USP 2%

Vaginal Antifungal

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

3 miconazole nitrate vaginal suppositories, USP 200 mg with 1 reusable applicator plus  
1 tube of miconazole nitrate vaginal cream, USP 2%

Net wt. oz (g)

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

Distributed by:

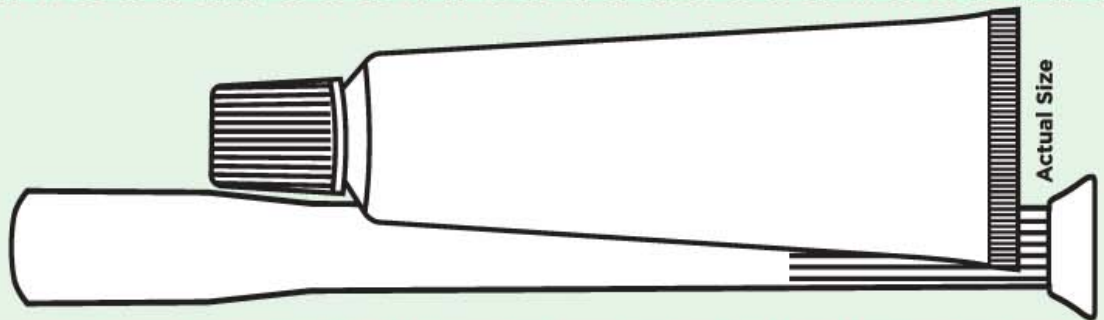
Wal-Mart Inc

Bentonville AR 72716

## **Package Label**

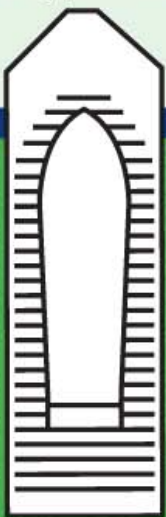


<p><b>Drug Facts</b></p> <p><b>Active Ingredients</b>          Miconazole nitrate, USP 2% (external cream)          Miconazole nitrate, USP 200 mg (in each suppository)          Vaginal antifungal</p> <p><b>Purpose</b>          Vaginal and vaginal</p> <p><b>Uses</b>          ■ treats vaginal yeast infections          ■ 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> <p>■ 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</p> <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>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</p> <p>Stop use and ask a doctor if ■ symptoms do not get better in 3 days          ■ symptoms last more than 7 days</p>	<p><b>Drug Facts (continued)</b></p> <p>■ you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling          vaginal discharge</p> <p>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.</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.          ■ 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)          ■ 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)</p> <p><b>Inactive ingredients</b>          suppository: hydrogenated vegetable oil          external cream: benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl          polyoxyglycerides, p-menthyl 7-stearate, purified water</p> <p><b>Questions?</b> 1-888-287-1915</p>
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NDC 49035-345-03

3 Suppositories



Actual Size

**equate™**

## 3 Day Treatment Miconazole Combination Pack

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

### Vaginal Antifungal

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

3 MICONAZOLE NITRATE VAGINAL SUPPOSITORIES, USP 200 MG WITH 3 DISPOSABLE  
 APPLICATORS PLUS 1 TUBE OF MICONAZOLE NITRATE VAGINAL CREAM, USP 2%

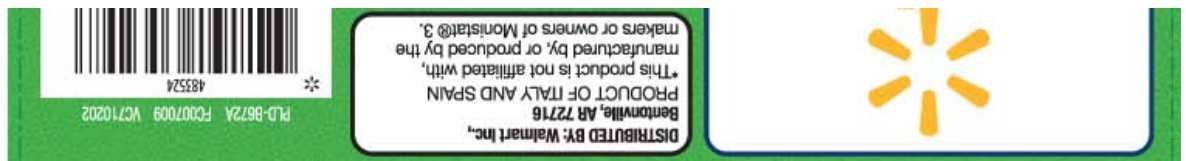
**NET WT 0.32 OZ (9g)**



**Compare to  
 Monistat® 3  
 Active  
 Ingredient\***



Satisfaction guaranteed - Or we'll replace it or  
 give you your money back. For questions or  
 comments or to report an undesired reaction or  
 side effect, please call 1-888-287-1915.



## EQUATE Miconazole 3 Day Combination Pack Treatment

### MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-345
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#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-345-03	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	05/01/2020	

#### 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
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#### 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	05/01/2020	

Part 2 of 2
<b>MICONAZOLE 3</b> miconazole nitrate cream

Product Information	
Route of Administration	VAGINAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>MICONAZOLE NITRATE</b> (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	10 mg in 0.5 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)	

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

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	05/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	05/01/2020	

**Labeler -** EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC) (051957769)

Revised: 12/2022

EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC)