

**TOPCARE MICONAZOLE 3 YEAST INFECTION RELIEF- miconazole nitrate cream**  
**Topco Associates LLC**

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**TopCare®**

**Miconazole 3 Yeast Infection Relief**

***Drug Facts***

**Active ingredient**

Miconazole Nitrate USP 4% (200 mg in each applicatorful)

**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**
- **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 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:
  - **applicators:** insert 1 applicatorful into the vagina at bedtime for 3 nights in a row. Throw applicator away after use.
- children under 12 years of age: ask a doctor

### **Other information**

- store at 20°-25°C (68°-77°F)
- do not purchase if carton is open
- see end flaps of carton and end of tube for lot number and expiration date
- the tube opening should be sealed. If seal has been broken, do not use product.

### **Inactive ingredients**

cetyl alcohol, isopropyl myristate, polysorbate 60, polysorbate 80, potassium hydroxide, propylene glycol, purified water, sorbitan monostearate and stearyl alcohol.

### **Questions?**

Call **1-888-423-0139**

DISTRIBUTED BY TOPCO ASSOCIATES LLC  
ELK GROVE VILLAGE, IL 60007

### **PRINCIPAL DISPLAY PANEL - 25 g Tube Carton**

TopCare  
health™

NDC 36800-070-09

COMPARE TO MONISTAT® 3  
ACTIVE INGREDIENT\*

3-DAY TREATMENT

Miconazole 3

MICONAZOLE NITRATE VAGINAL CREAM USP (4%)  
(MICONAZOLE NITRATE 200 MG PER APPLICATOR)

VAGINAL ANTIFUNGAL

- CURES Most Vaginal YEAST INFECTIONS

Consumer Information Leaflet Enclosed

ONE 0.9 OZ (25 g) TUBE OF 3 DAY VAGINAL CREAM & 3 DISPOSABLE APPLICATORS

**3-DAY TREATMENT**

- CURES Most Vaginal YEAST INFECTIONS



3 Disposable Applicators

**3-DAY TREATMENT**

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NDC36800-070-09



**COMPARE TO MONISTAT® 3  
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DISTRIBUTED BY TOPCO ASSOCIATES LLC  
ELK GROVE VILLAGE, IL 60007  
© TOPCO TARA0819 QUESTIONS? 1-888-423-0139  
topcare@topco.com www.topcarebrand.com  
MADE IN CANADA

TAMPER-EVIDENT UNIT  
DO NOT USE IF SEAL OVER TUBE  
OPENING HAS BEEN PUNCTURED.



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

\*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Monistat® 3.



Scan here for more information

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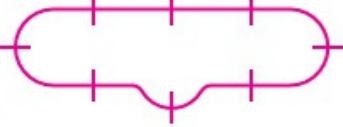
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**3-DAY TREATMENT**  
**Miconazole 3**  
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**TopCare**  
health™

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**Miconazole 3**  
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**NO COPY ON THIS FLAP  
FOR LOT # AND EXPIRY  
DATE PRINT**

LPK-6809-2  
0819-2  
16

T128B

**Drug Facts**

**Active ingredient**  
Miconazole Nitrate USP 4% (200 mg in each applicator),....., Vaginal antifungal

**Use**  
• treats vaginal yeast infections

**Warnings**  
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For vaginal use only

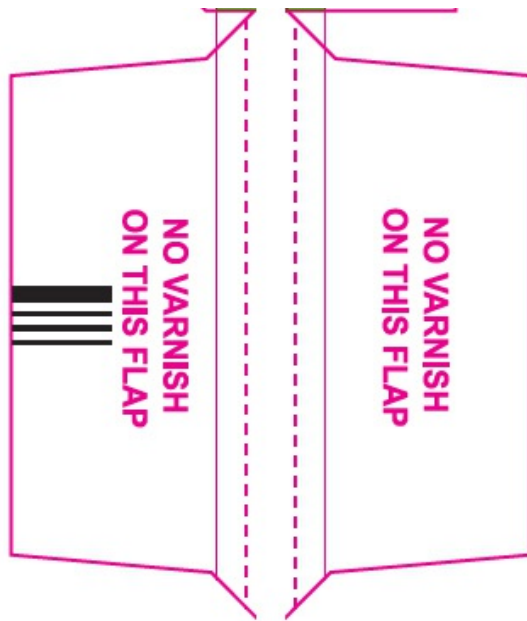
Ask a doctor before use if you have  
• vaginal itching and discomfort for the first time  
• lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting or  
foul-smelling vaginal discharge. You may have a more serious condition.  
• vaginal yeast infections often (such as once a month or 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.

**Drug Facts** (continued)

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## TOPCARE MICONAZOLE 3 YEAST INFECTION RELIEF

miconazole nitrate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-070
<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	40 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)	
<b>polysorbate 60</b> (UNII: CAL22UVI4M)	
<b>polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>potassium hydroxide</b> (UNII: WZH3C48M4T)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>water</b> (UNII: 059QF0K00R)	
<b>sorbitan monostearate</b> (UNII: NVZ4I0H58X)	
<b>stearyl alcohol</b> (UNII: 2KR89I4H1Y)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-070-	1 in 1 CARTON	01/16/2013	

1	09	1 in 1 CARTON	01/10/2019	
1		25 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA076773		03/02/2005	

**Labeler** - Topco Associates LLC (006935977)

Revised: 10/2019

Topco Associates LLC