# PREMIER VALUE MICONAZOLE 3- miconazole nitrate cream Pharmacy Value Alliance LLC

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#### Premier Value<sup>®</sup> Miconazole 3

**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 1-866-923-4914

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

# PRINCIPAL DISPLAY PANEL - 25 g Tube Carton

#### Consumer Information Leaflet Enclosed

# **3 DAY TREATMENT**

**Cures Most Vaginal Yeast Infections** 

Premier Value<sup>®</sup>

# **MICONAZOLE 3**

Miconazole Nitrate Vaginal Cream USP (4%) (Miconazole Nitrate 200 mg per applicator) **Vaginal Antifungal** 

One 0.9 oz (25 g) tube of 3 Day Vaginal Cream with 3 Disposable Applicators

INDEPENDENTLY TESTED PV SATISFACTION GUARANTEED



## PREMIER VALUE MICONAZOLE 3

miconazole nitrate cream

Product Information									
P	roduct T ype		HUMAN OTC DRUG It		Code (Source)		NDC:68016-070		
R	oute of Administr	ation	VAGINAL						
Active Ingredient/Active Moiety									
	Ingredient Name Basis of						rength	Strength	
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M) Miconazol						Miconazole N	itra te	40 mg in 1 g	
Inactive Ingredients									
Ingredient Name							Strength		
cetyl alcohol (UNII: 936JST6JCN)									
isopropyl myristate (UNII: 0 RE8 K4LNJS)									
polysorbate 60 (UNII: CAL22UVI4M)									
polysorbate 80 (UNII: 6OZP39ZG8H)									
potassium hydroxide (UNII: WZH3C48M4T)									
propylene glycol (UNII: 6DC9Q167V3) water (UNII: 059QF0KO0R)									
sorbitan monostearate (UNII: NVZ4I0H58X)									
stearyl alcohol (UNII: 2KR8914H1Y)									
Packaging									
#	Item Code	em Code Package Description		M	Marketing Start Ma Date		rketing End Date		
	NDC:68016-070- 09				03/0	03/02/2005			
1		25 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product							
Marketing Information									
N	larketing Catego	ry Applicatio	ation Number or Monograph Citation		Marketing Start Date		Marketing End Date		
ANDA		ANDA076773	DA076773		03/02/2005				

Labeler - Pharmacy Value Alliance LLC (101668460)

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Pharmacy Value Alliance LLC