

**FREDS MICONAZOLE 3- miconazole nitrate cream**  
**FRED'S, INC.**

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**Fred's**  
**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: fred's, Inc.**  
**4300 NEW GETWELL RD,**  
**MEMPHIS, TN 38118**

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

fred's  
Pharmacy

Cures Most Vaginal  
Yeast Infections

3 Day  
Treatment

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

Consumer  
Information  
Leaflet Enclosed



**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55315-737
<b>Route of Administration</b>	VAGINAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Miconazole Nitrate</b> (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	40 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<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**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55315-737-43	1 in 1 CARTON	12/20/2018	
1		25 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

**Marketing Information**

<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** - FRED'S, INC. (005866116)

Revised: 1/2019

FRED'S, INC.