

**FEMMESIL CREME MAXIMUM STRENGTH- miconazole nitrate cream**  
**Aidance Skincare & Topical Solutions, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts**

**Active Ingredient**

Miconazole Nitrate 2%

**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; if you have a fever (higher than 100° F), pain in the lower abdomen, back, or either shoulder, or a foul-smelling vaginal discharge. You should see a doctor for treatment of these symptoms.

**Ask 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.

**When using this product**

- Do not use tampons, douches, spermicides, or other vaginal products; condoms or diaphragms may be damaged and fail to prevent sexually transmitted disease or pregnancy.
- 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 a foul-smelling vaginal discharge.

**Directions**

Children under 12	Ask a physician
Adults and children 12 years and	Femmesil may be used topically (outside the vaginal area) or intravaginally. Squeeze a small amount of cream onto fingertip. Apply 2-3 times daily for up to 3 days or longer,

over as needed.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.**

If swallowed, call poison control or seek medical help.

**Other Information**

Store at room temperature.

**Inactive Ingredients**

bentonite clay, distilled water, jojoba seed oil, peppermint oil, silver oxide, tea tree oil, zinc oxide.

**Questions?** 877-4-AIDANCE

**PRINCIPAL DISPLAY PANEL - 28g Carton**

All-Natural Cure for Vaginal Itch, Odor and Yeast Infection

**femmesil**  
with Activated Minerals™  
creme

New Advanced Formula

**Drug Facts (continued)**

**Warnings**  
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**Drug Facts**

**Active Ingredient:**  
Miconazole Nitrate 2%




**Purpose:**  
Vaginal Antifungal

**Use:** Treats vaginal yeast infections

**For warnings, see back of box**


**Directions**

Children under 12	Ask a physician.
Adults and children 12 years and over	Femmesil may be used topically (outside the vaginal area) or intravaginally. Squeeze a small amount of cream onto fingertip. Apply 2-3 times daily for up to 3 days or longer, as needed.

**AidanceSkincare**

**MAXIMUM STRENGTH**  
New Advanced Formula



with Activated Minerals™  
**femmesil**  
creme

All-Natural Cure for Vaginal Itch,  
Odor and Yeast Infection

Restores Natural Vaginal Balance  
& Relieves Multiple Symptoms

Net wt. 28 grams

**Drug Facts (continued)**

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, call poison control or seek medical help.


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Store at room temperature.

**Inactive Ingredients:**  
bentonite clay, distilled water, jojoba seed oil, peppermint oil, silver oxide, tea tree oil, zinc oxide

**Questions? 877-4-AIDANCE**

Made in USA. Manufactured by Aidance Skincare. [www.aidance.com](http://www.aidance.com)

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**AidanceSkincare**

## FEMMESIL CREME MAXIMUM STRENGTH

miconazole nitrate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24909-201
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2.0 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
JOJOBA OIL (UNII: 724GKU717M)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SILVER OXIDE (UNII: 897WUN6G6T)	
TEA TREE OIL (UNII: VIF565UC2G)	
WATER (UNII: 059QF0KO0R)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-201-28	1 in 1 CARTON		
1		28 g in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/07/2012	

**Labeler** - Aidance Skincare & Topical Solutions, LLC (018950611)

### Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-201) , label(24909-201)

Revised: 9/2012

Aidance Skincare & Topical Solutions, LLC