

FEMMESIL MAXIMUM STRENGTH- miconazole nitrate ointment

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.

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	Femmesil may be used topically (outside the vaginal area) or intravaginally. Squeeze a small amount of cream onto

years and over	fingertip. Apply 2-3 times daily for up to 3 days or longer, as needed.
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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

beeswax (organic), bentonite clay, cotton seed oil, jojoba seed oil, magnesium oxide, peppermint oil, silver oxide, stearic acid, tea tree oil, zinc oxide.

Questions? 877-4-AIDANCE

PRINCIPAL DISPLAY PANEL - 25g Tube

Maximum Strength

femmesil
ultra therapy

All-Natural Cure for Vaginal Itch, Odor and Infection

NET WT 28 g FDA Registered

DRUG FACTS
Active Ingredient and Purpose: Miconazole Nitrate 2% 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 a doctor 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. • May increase in vaginal burning, itching, or irritation may occur. **Stop use and ask a doctor if symptoms do not improve 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. 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.**
Directions: Children under 12: Ask a physician. Adults and Children 12 years and older: Femmesil may be used topically (outside the vaginal area) or intravaginally. Squeeze a small amount of cream onto fingertip. Apply 2 to 3 times daily for up to 3 days or longer as needed. Store at room temperature. **Inactive Ingredients:** beeswax (organic), bentonite clay*, cotton seed oil, jojoba seed oil, magnesium oxide, peppermint oil, silver oxide, tea tree oil, vegetable stearic acid (naturally sourced), zinc oxide. *May contain this ingredient.
Questions? 401-432-7790 or www.aidance.com. Manufactured by Aidance Skincare, Copyright © 2018 Aidance Scientific, LLC. All rights reserved. Femmesil is protected by numerous US and international patents granted and pending. Aidance®, Femmesil® and Activated Minerals® are registered trademarks of Aidance Skincare & Topical Solutions, LLC.

FEMMESIL MAXIMUM STRENGTH

miconazole nitrate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-202
Route of Administration	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)	
COTTONSEED OIL (UNII: H3E878020N)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SILVER OXIDE (UNII: 897WUN6G6T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TEA TREE OIL (UNII: VIF565UC2G)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-202-28	1 in 1 CARTON	09/07/2012	
1		28 g in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:24909-202-29	28 g in 1 TUBE; Type 0: Not a Combination Product	12/31/2018	

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(24909-202) , label(24909-202)