FEMMESIL MAXIMUM STRENGTH- miconazole nitrate ointment Aidance Skincare & Topical Solutions, LLC

24909-202 femmesil

Active Ingredient

Miconazole Nitrate 2%.

Purpose

Vaginal Antifungal.

Use.

Treats vaginal yeast infections

Warnings

For vaginal use only. Do not useif 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 ifsymptoms do not get better in 3 days; symptoms last more than 7 days; you get a rash orhives, abdominal pain, fever, chills, nausea, vomiting or a foul-smelling vaginal discharge.

Directions

Children under 12	Ask a physician
children	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.

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

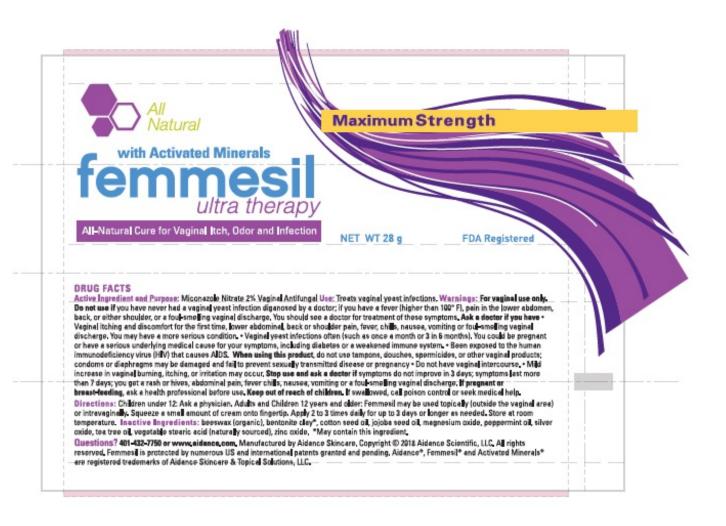
Store at room temperature

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 - 28g Tube



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: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) MICONAZOLE NITRATE | 2 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
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)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:24909-202- 28	1 in 1 CARTON	09/07/2012	06/01/2017	
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 Drug	M005	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)		

Revised: 5/2024 Aidance Skincare & Topical Solutions, LLC