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 orhives, abdominal pain, fever, chills, nausea, vomiting or a foul-smelling vaginal discharge.

Directions

Children under 12	Ask a physician
	Femmesil may be used topically (outside the vaginal area) or intravaginally. Squeeze a small amount of cream onto

years and	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

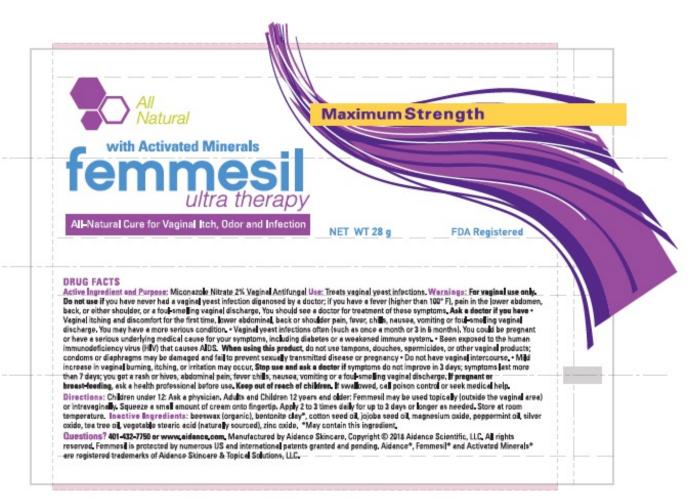
Store at room temperature

Inactive Ingredients

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



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		
MICO NAZO LE NITRATE (UNII: VW4H1CYW1K) (MICONAZO LE - UNII:7NNO 0 D7S5M)	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 O XIDE (UNII: 3A3U0 GI71G)				
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)				

F	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)