

FEMMESIL- clotrimazole 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.

Drug Facts

Active Ingredient

Clotrimazole 1%

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

Cotton seed oil, distilled water, emulsifying wax, jojoba seed oil, peppermint oil, shea butter, silver oxide, sorbic acid, stearic acid, tea tree oil, zinc oxide.

Questions? 401-432-7750

PRINCIPAL DISPLAY PANEL - 50g Tube



FEMMESIL
clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
COTTONSEED OIL (UNII: H3E878020N)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
JOJOBA OIL (UNII: 724GKU717M)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SHEA BUTTER (UNII: K49155WL9Y)	
SILVER OXIDE (UNII: 897WUN6G6T)	
SORBIC ACID (UNII: X045WJ989B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TEA TREE OIL (UNII: VIF565UC2G)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-203-25	1 in 1 CARTON	11/30/2014	
1		25 g in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:24909-203-50	50 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	11/30/2014	

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

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-203) , label(24909-203)