

FEMMESIL- clotrimazole cream
Aidance Skincare & Topical Solutions, LLC

24909-203 femmesil Cream

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, either shoulder, or a foul-smelling vaginal discharge. You should see a doctor for treatment of these symptoms.

Ask a 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 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.

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 to 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. May temporarily (washable) discolor skin and fabrics in sunlight.

Inactive Ingredients

cottonseed oil, purified water, emulsifying wax, jojoba oil, peppermint oil, shea butter, silver stearate, sorbic acid, tea tree oil, zinc oxide

Questions?401-432-7750

PRINCIPAL DISPLAY PANEL - 50g Tube



Natural

with Activated Minerals® femmesil cream

A Soothing Natural Cream for Vaginal Itch, Odor & Infection

Restores Natural Vaginal Balance & Relieves Multiple Symptoms

Clotrimazole 1%

New Advanced Formula

NET WT. 1.7 oz

Drug Facts

Active ingredient

Clotrimazole 1% Vaginal Antifungal

Purpose

Uses: 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, either shoulder, or a foul-smelling vaginal discharge. You should see a doctor for treatment of these symptoms. **Ask a 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 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 over - 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. May temporarily (wash/discard) skin and fabrics in sunlight.

Inactive ingredients: cottonseed oil, purified water, emulsifying wax, jojoba oil, peppermint oil, Shea butter, silver stearate, sorbic acid, tea tree oil, zinc oxide

Questions? 401-432-7750 or www.aidance.com

Manufactured by Aidance Scientific, Inc. (DBA Aidance Skincare & Topical Solutions), Woonsocket, RI. Copyright ©2014, 2023 Aidance Scientific, Inc. All rights reserved. Femmesil is protected by numerous U.S. and international patents granted and pending.
2690 NDC 24909-203-50 UPC 1 87451 00055 8

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 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
COTTONSEED OIL (UNII: H3E878020N)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
JOJOBA OIL (UNII: 724GKU717M)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SHEA BUTTER (UNII: K49155WL9Y)	
SILVER STEARATE (UNII: 4H6PCL92ZN)	
SORBIC ACID (UNII: X045WJ989B)	
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	06/01/2017
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 Drug	M005	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)

Revised: 5/2024

Aidance Skincare & Topical Solutions, LLC