

MICONAZOLE NITRATE - miconazole nitrate cream
Central Texas Community Health Centers

Miconazole nitrate

ACTIVE INGREDIENT

Miconazole nitrate 2% (100 mg in each applicator)
Miconazole nitrate 2% (as external cream)

PURPOSE

Vaginal antifungal

USES

- treats repeat vaginal yeast infections
- relieves external itching and irritation due to a repeat vaginal yeast infection

WARNINGS

For vaginal use only

Do not use if you have never had a vaginal yeast infection diagnosed by a doctor

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.

Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medication warfarin, because bleeding or bruising may occur.

When using this product

- do not use tampons, douches, spermicides, or other vaginal products
- do not have vaginal intercourse
- condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs)

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 foul-smelling vaginal discharge

IF PREGNANT OR BREAST FEEDING,

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION

- before using this product read the enclosed consumer information leaflet for complete instructions
- adults and children 12 years of age and over:
 - **applicator:** insert one applicatorful into the vagina at bedtime for 7 nights in a row
 - **external cream:** squeeze a small amount of cream onto your fingertip. Gently apply the cream onto the itchy, irritated skin outside the vagina. Use daily for up to 7 days as needed
- children under 12 years of age: ask a doctor

OTHER INFORMATION

- do not use if seal over tube opening has been punctured or cannot be seen
- store at room temperature 15°-30°C (59°-86°F). Avoid heat over 30°C or 86°F.

INACTIVE INGREDIENT

benzoic acid, BHA, mineral oil, peglicol 5 oleate, pegoxol 7 stearate, purified water

PRINCIPAL DISPLAY PANEL - 45 g Tube Label

CommUnityCare Federally Qualified Health Centers

MICONAZOLE
2% VAGINAL
CREAM

Date:

Name:

Dr.

USE AS DIRECTED

123456

1/1/01

MICONAZOLE 2% VAG.CRM 45gNDC 76413-318-45

Batch: 123456

Lot: 123456

Exp: 1/1/01

G&W LABS

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

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MICONAZOLE NITRATE

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-318(NDC:0713-0252)
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Benzoic Acid (UNII: 8SKN0B0MIM)	
Butylated Hydroxyanisole (UNII: REK4960K2U)	
Mineral Oil (UNII: T5L8T28FGP)	
Peg-5 Oleate (UNII: 0240V77G50)	
Pegoxol 7 Stearate (UNII: 3EW5AXE5X5)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-318-45	1 in 1 CARTON	02/22/1996	
1		45 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074366	02/22/1996	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-318) , RELABEL(76413-318)

Revised: 4/2016

Central Texas Community Health Centers