

**MICONAZOLE NITRATE- miconazole nitrate cream**  
**Rebel Distributors Corp**

*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.*

-----  
**Miconazole Nitrate 2% Drug Facts**

**Active ingredient**

Miconazole Nitrate 2% (100 mg in each applicator)

**Purpose**

Vaginal antifungal

**Keep Out of Reach of Children**

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

**Uses**

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

**Warnings**

For vaginal use only

Ask a doctor before use if you have

- . never had a vaginal yeast infection diagnosed by a doctor
- . 1 or more of the following:

abdominal pain, fever, chills, nausea, vomiting, foul-smelling vaginal discharge

- . vaginal yeast infections often (such as once a month or 3 in 6 months)

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

If pregnant or breast-feeding, ask a health professional before use.

**Other Information**

- . do not purchase if printed "Safety Sealed" carton  
overwrap is broken or missing

- . 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.

### Directions

- . 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

### Inactive ingredients

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

### Package/Label Principal Display Panel



## MICONAZOLE NITRATE

miconazole nitrate cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-854(NDC:0713-0252)
Route of Administration	VAGINAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MM)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-854-45	45 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/01/2008	

**Labeler** - Rebel Distributors Corp (118802834)

## Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011

Rebel Distributors Corp