

**MICONAZOLE 7- miconazole nitrate cream
Cardinal Health (Leader) 70000**

Miconazole Nitrate Vaginal Cream, USP

Drug Facts

Active ingredient

Miconazole nitrate, USP 2% (100 mg in each applicator)

Purpose

Vaginal antifungal

Uses

- treats vaginal yeast infections
- relieves external itching and irritation due to a 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 medicine warfarin, because bleeding or bruising may occur

When using this product

- do not use tampons, douches, spermicides or other vaginal products. Condoms and

diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).

- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur
- if you do not get complete relief ask a doctor before using another product.

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 (1-800-222-1222) right away.

Directions

- before using this product read the enclosed consumer information leaflet for complete directions and information
- **adults and children 12 years of age and over:**
 - **applicator:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Wash applicator after use.
 - use the same tube of cream if you have itching and irritation on the skin outside the vagina. Squeeze a small amount of cream onto your fingertip. Apply to itchy, irritated skin outside the vagina (vulva). Use 2 times daily for up to 7 days as needed.
- **children under 12 years of age: ask a doctor**

Other information

- to open tube: unscrew cap, lift tab, and pull to remove foil seal prior to use
- do not use if foil seal on tube opening is broken or missing
- do not purchase if carton is open
- store at room temperature 20°-25°C (68-77°F)
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxyglycerides, pegoxol 7 stearate, purified water

Question?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal display panel

COMPARE TO MONISTAT® 7 VAGINAL CREAM active ingredient*

Miconazole 7

Miconazole Nitrate Vaginal Cream, USP 2%

(Miconazole Nitrate 100 mg per applicator)

Vaginal Antifungal

Cures Most Vaginal Yeast infections

Relieves Associated External Itching and Irritation

7 DAY VAGINAL CREAM (1 TUBE)

WITH 1 REUSABLE APPLICATOR

NET WT OZ (g)

*This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat®.

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

Package label

This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat®.

Drug Facts (continued)

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Inactive ingredients benzoic acid, butylated hydroxytoluene, mineral oil, oleoyl polyoxyglycerides, povidone 7 sterate, purified water

Questions? Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

Drug Facts

Active ingredient Miconazole nitrate USP, 2% (100 mg in each applicator),..... Vaginal antifungal

Purpose

■ treats yeast infections

■ relieves external itching and irritation due to a 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.

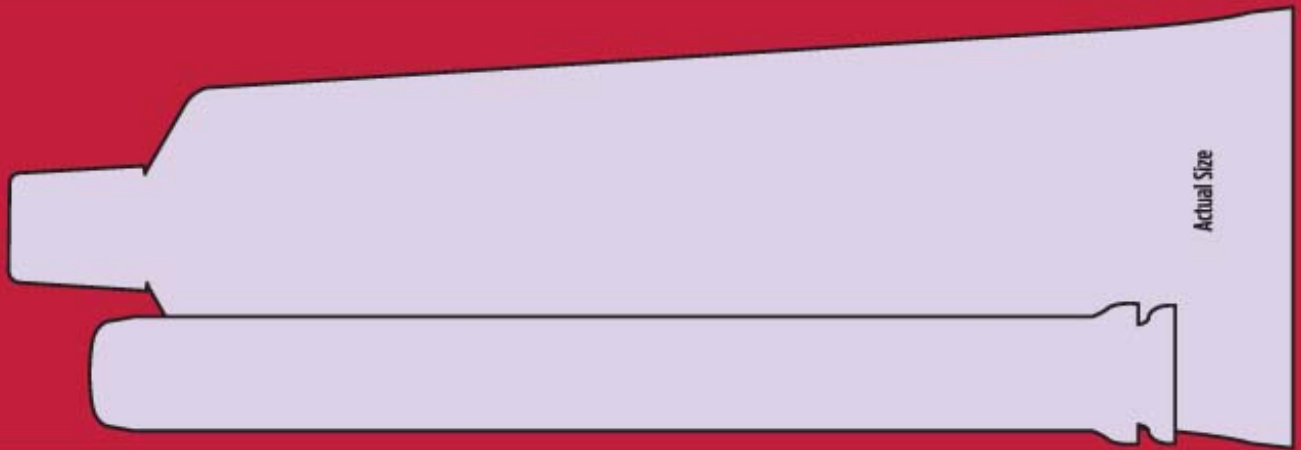
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LEADERTM

NDC 70000-0009-1

Miconazole 7

Miconazole Nitrate Vaginal Cream, USP 2%
(Miconazole Nitrate 100 mg per applicator)
Vaginal Antifungal

Cures Most Vaginal Yeast Infections
Relieves Associated External Itching and Irritation

7 DAY VAGINAL CREAM (1 TUBE)
WITH 1 REUSABLE APPLICATOR

NET WT 1.59 OZ (45 g) TUBE

COMPARE TO
MONISTAT[®] 7
VAGINAL CREAM
active ingredient*

100% Money
Back Guarantee





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1-800-200-6313
Essential to Care™ since 1979
Product of India

CIN 5519418 REV. 2/24



Code: 60/DRUGS/361 AAJ3A/06 PLD-E665C FC009039

All LEADER™ Brand Products Have A 100% Money Back Guarantee
Return to place of purchase if not satisfied.

LEADER Vaginal Antifungal

MICONAZOLE 7

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0009
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)	
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0009-1	1 in 1 CARTON	07/01/2019	

1	45 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074164	07/01/2019	

Labeler - Cardinal Health (Leader) 70000 (063997360)

Revised: 3/2024

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