MICONAZOLE 7- miconazole nitrate cream Rite Aid Corporation

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. Throw applicator away 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° to 25°C (68° to 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 polyoxylglycerides, pegoxol 7 stearate, purified water

Question?

Call 1-877-735-3935 Monday-Friday 9AM-5PM EST

Principal display panel

Compare to the active ingredient in Monistat® 7 Vaginal Cream*

Miconazole 7

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

VAGINAL ANTIFUNGAL

7 - DAY TREATMENT

Cures most vaginal yeast infections

Relieves associated external itching and irritation

NET WT OZ (g) Tube

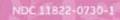
*This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat®

DISTRIBUTED BY: RITE AID,

200 NEWBERRY COMMONS

ETTERS, PA 17319

Package label





Compare to the active ingredient in Monistat* 7 Vaginal Cream*

7-DAY TREATMENT

1 Tube with 7 Disposable Applicators





7 DISPOSABLE APPLICATORS . ACTUAL SIZE

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

7-DAY TREATMENT

Cures most vaginal yeast infections Relieves associated external itching and irritation



7 DAY VAGINAL CREAM (1 TUBE) NET WT 1.59 OZ (45 g) TUBE WITH 7 DISPOSABLE APPLICATORS

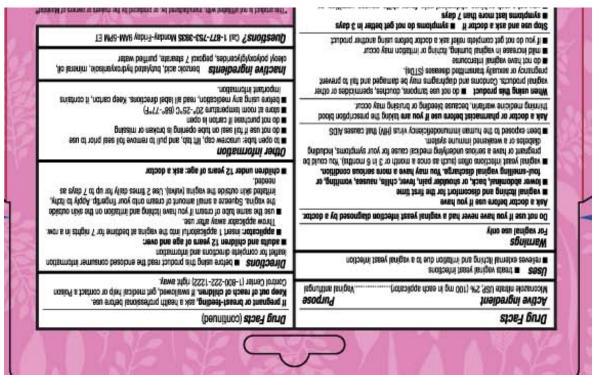


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RITE AID Vaginal Antifungal Treatment

MICONAZOLE 7

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0730
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: 85KN0B0MIM)		
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		

I	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:11822-0730-1	1 in 1 CARTON	03/01/2001	
	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	03/01/2001	

Labeler - Rite Aid Corporation (014578892)

Revised: 4/2024 Rite Aid Corporation