MICONAZOLE 7- miconazole nitrate cream QUALITY CHOICE (Chain Drug Marketing Association)

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 foulsmelling 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 foulsmelling 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 polyoxylglycerides, pegoxol 7 stearate, purified water

Questions?

Call 1-800-935-2362 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%

Vaginal Antifungal

(Miconazole Nitrate 100 mg per applicator)

Cures Most Vaginal Yeast Infections and Relieves

Associated External Itching and Irritation

OZ NET WT (g) Tube Vaginal Cream with Reusable Applicator

*This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat $\ensuremath{\mathbb{R}}$.

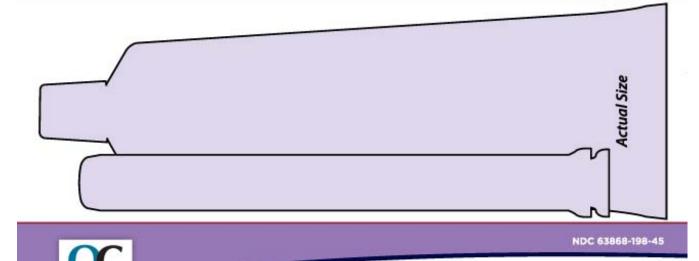
Distributed by CDMA, Inc.

Novi, MI 48375

www.qualitychoice.com

Package label

Stop use and sak a doctor iff m symptoms do not get better in 3 days a symptoms last more than 7 days m you get a resh or three, abdominal pain, fever, chills, nausae,	"This product is not affiliated with, manufactured by, or produced by the makers or owners of Montatat ⁴ .	
and the second	Questions? Call 1-800-836-2362 Montay-Friday 9AM-5PM EST	
When using this product a do not use tampore, doubled, sperver pregnancy or security hermitolds, to obtactive ing condons and depregnance or security instruction optimes descarses condons and balance or security in the conducts, approximation optimes descarses condons and balance of the conducts a do not have veginal interva	inactive ingredients beraxic sold, buykated hydroxyanisole, minaral ol, oleoyi polycrytgycandee, pegoool 7 atearate, puritied water	
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Been exposed to the human immodeficiency virus (File) that causes AUCS serious underlying medical cause for your symptoms, including database of a weakened immune system.	Other information — to open tube: unearew cap, lift bib, and pull to remove foil seal prior to use = do not use if holl seal on tube opening is broken or missing = do not purchase if carbin is open = do not purchase if a purc	
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Miconazole 7 Miconazole Nitrate Vaginal Cream USP, 2%

Vaginal Antifungal

QUALITY

(Miconazole Nitrate 100 mg per applicator)

Cures Most Vaginal Yeast Infections and Relieves Associated External Itching and Irritation

1.59 OZ NET WT (45 g) Tube

7 Day Vaginal Cream (1 Tube) with 1 Reusable Applicator



Distributed by CDMA, Inc. Novl, MI 48375 www.qualitychoice.com Questions: 800-935-2362 Code: GO/DRUGS/361 AAL3A/04

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QUALITY CHOICE Vaginal Antifungal Cream

MICONAZO									
miconazole nitrate cream									
Product Info	ormation								
Product Type		HUMAN OTC DRUG	ltem Co	Item Code (Source)		NDC:63	NDC:63868-198		
Route of Admi	nistration	VAGINAL							
Active Ingree	Active Ingredient/Active Moiety								
Active higher		dient Name			Basis of Str	onath	Strongth		
MICONAZOLE NI		H1CYW1K) (MICONAZ	OLE -			-			
UNII:7NNO0D7S5M				LE - MICONAZOLE NIT			20 mg in 1 g		
Inactive Ingredients									
j.		Ingredient Na	me			S	strength		
BENZOIC ACID (UNII: 85KN0B0MIM	-					5		
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 Cha	racteristics								
Color		white	Score						
Shape			Size						
Flavor			Imprint Code						
Contains									
Packaging									
				Mar	keting Start	Marl	ceting End		
# Item Code	Pa	ickage Descript	ion	Man	Date	Man	Date		
1 NDC:63868- 198-45	1 in 1 CARTON			07/01,	/2010				
1	45 g in 1 TUBE, V Combination Proc	MTH APPLICATOR; Typ duct	pe 0: Not a						

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
ANDA	ANDA074164	07/01/2010					

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 9/2022

QUALITY CHOICE (Chain Drug Marketing Association)