

MICONAZOLE 7- miconazole nitrate cream
Chain Drug Consortium, LLC

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) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°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

Questions?

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

Principal display label

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

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:

Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,

Wayne, PA 19087

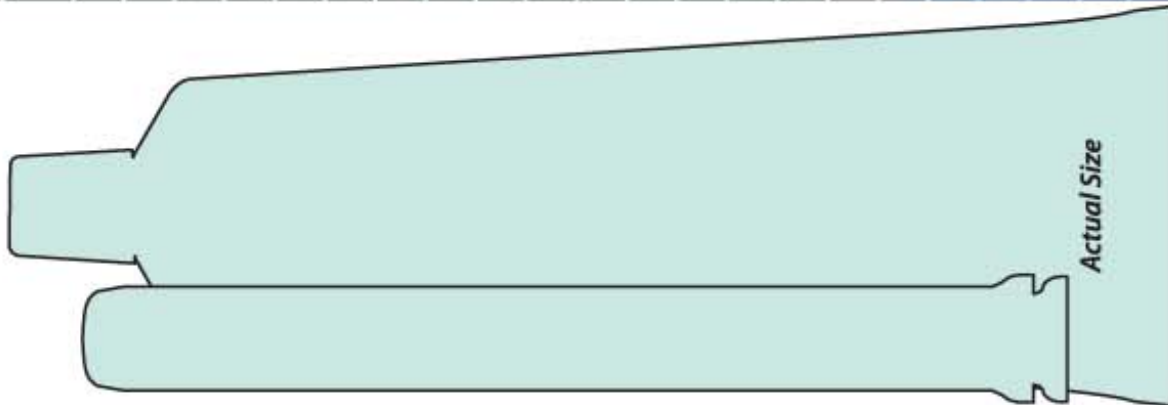
Package label



1 Tube and
1 Reusable Applicator

Miconazole 7

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



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**

7 Day Vaginal Cream (1 Tube)
with 1 reusable applicator

NET WT 1.59 OZ (45 g) TUBE



Distributed by:
Pharmacy Value Alliance, LLC
407 East Lancaster Avenue,
Wayne, PA 19087



If for any reason you are not satisfied with
this product, please return it to the store
where purchased for a full refund.

PLD-8655B FC007310



8 40986 01125 2

Code: GO/DRUGS/361 AAK3A/03

Drug Facts	
Active ingredient	Miconazole nitrate USP, 2% (100 mg in each applicator);.....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.	■ 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
4	
Drug Facts (continued)	
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. ■ 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) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°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
Questions?	Call 1-877-753-3935 Monday-Friday 9AM-5PM EST
*This product is not affiliated with, manufactured by, or produced by the makers or owners of Monestar.	

PREMIER VALUE Miconazole Nitrate Vaginal Cream

MICONAZOLE 7

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-073
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:68016-073-01	1 in 1 CARTON	09/11/2003	
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	09/11/2003	

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 11/2022

Chain Drug Consortium, LLC