# MICONAZOLE 7- miconazole nitrate cream P & L Development, LLC

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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 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 temperate 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

#### **Questions?**

Call 1-877-753-3935 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

- cures most vaginal yeast infections
- relieves associated external itching and irritation

net wt. oz (g) tube

7 day vaginal cream (1 tube)

+ 1 reusable applicator

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

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

# Package label



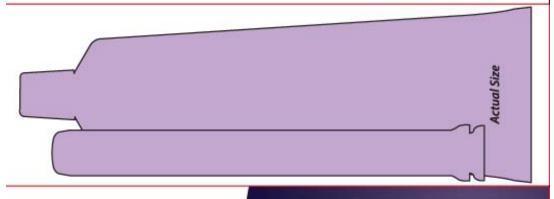


miconazole nitrate vaginal cream, USP 2%

(miconazole nitrate 100 mg per applicator)

vaginal antifungal

7 day vaginal cream (1 tube) with 1 reusable applicator





- miconazole 7
  - miconazole nitrate vaginal cream, **USP 2%**

(miconazole nitrate 100 mg per applicator)

Compare to the active ingredient in Monistat® 7 Vaginal Cream

NDC 59726-988-01

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

# miconazole 7

miconazole nitrate vaginal cream, USP 2%

(miconazole nitrate 100 mg per applicator)

vaginal antifungal

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Distributed by: No Hicks Street Westbury, NY 11590 Westbury, NY 11590

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Drug Facts	Dung Facts (continued)	

# READYinCASE Vaginal Antifungal

## **MICONAZOLE 7**

miconazole nitrate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-988	
Route of Administration	VAGINAL			

# Active Ingredient/Active Moiety Ingredient Name Basis of 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				

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59726- 988-01	1 in 1 CARTON	05/28/2021			
1		45 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product				

Marketing I	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA074164	05/28/2021			

# Labeler - P & L Development, LLC (800014821)

Revised: 11/2022 P & L Development, LLC