

**MICONAZOLE 3 COMBINATION PACK- miconazole nitrate  
P & L Development, LLC**

-----  
**Miconazole 3 Combination Pack**

***Drug Facts***

***Active ingredients***

Miconazole nitrate, USP 200 mg (in each suppository)  
Miconazole nitrate, USP 2% (external cream)

***Purpose***

Vaginal antifungal

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

**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:**
  - **suppositories:** insert 1 suppository into the vagina at bedtime for 3 nights in a row. Wash applicator away after use.
  - **external cream:** Use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Gently apply the cream onto the itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days, as needed.
- **children under 12 years of age: ask a doctor**

**Other information**

- do not use if suppository wrapper is missing or damaged (each suppository is individually wrapped)
- do not use if seal over tube opening has been punctured or is not visible
- do not purchase if carton is open
- store at 20° - 25°C (68° - 77°F) [see USP controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F)

**Inactive ingredients**

- suppository: hydrogenated vegetable oil
- external cream: 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 Panel**

Compare to the active ingredient in Monistat® 3\*

### **miconazole nitrate**

Miconazole nitrate vaginal antifungal cream, USP 2%  
and Miconazole nitrate vaginal suppositories, USP 200 mg

vaginal antifungal

combination pack

3 day treatment

- Cures most vaginal yeast infections
- Relieves associated external itching and irritation

net wt. oz (g) tube

+ 3 suppositories with 3 disposable applicators

\*This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat® 3.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

## **Package Label**



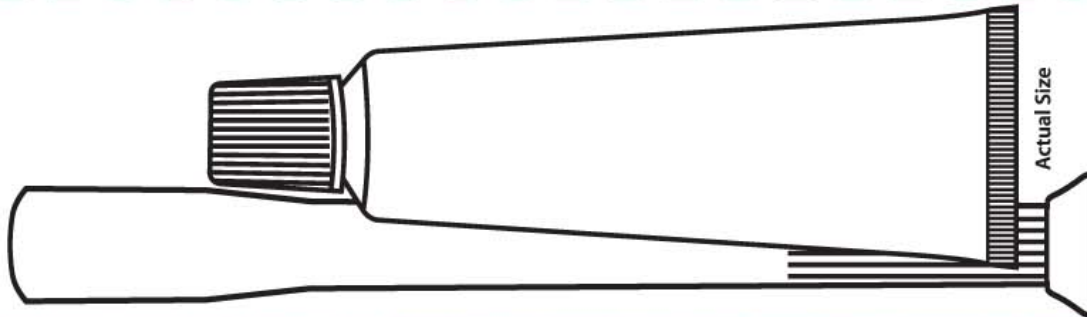
# miconazole nitrate

miconazole nitrate vaginal antifungal cream,  
USP 2%  
and miconazole nitrate vaginal suppositories,  
USP 200 mg

## 3 day treatment

3 day vaginal cream (1 tube)  
+ 3 suppositories with 3 disposable applicators

vaginal antifungal  
combination pack



Compare to the active ingredient in  
**Monistat® 3\***

NDC 59726-989-03

# miconazole nitrate

miconazole nitrate vaginal antifungal cream,  
USP 2%  
and miconazole nitrate vaginal suppositories,  
USP 200 mg

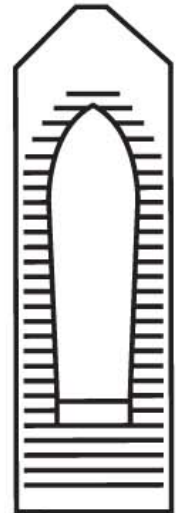
## 3 day treatment

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

net wt. 0.32 oz (9 g) tube  
+ 3 suppositories with 3 disposable applicators

vaginal antifungal  
combination pack

3 Suppositories



Actual Size



Distributed by:  
**PL Developments**  
200 Hicks Street  
Westbury, NY 11590

PLD-A672A FC007772 VC710347



3 59726 98902 2

\*This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat® 3.

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

CAUTION: For vaginal use only. Do not use if you are pregnant, nursing, or have a yeast infection. Avoid sexual intercourse during treatment. See package insert for complete directions. Keep out of reach of children. Do not use if the seal is broken or the applicator is damaged.

**Drug Facts**

**Active ingredients**  
Miconazole nitrate, USP 200 mg (in each suppository);  
Miconazole nitrate, USP 2% (external cream);  
Vaginal antifungal  
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  
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:  
■ suppositories: insert 1 suppository into the vagina at bedtime for 3 nights in a row. Throw applicator away after use.  
■ external cream: use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Apply to itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days.  
■ children under 12 years of age: ask a doctor  
**Other information** ■ do not use if seal over tube opening has been punctured or is not visible  
■ do not use if seal over tube opening has been punctured or is not visible  
■ do not purchase if carton is open  
■ store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F)  
**Inactive ingredients**  
suppository - hydrogenated vegetable oil  
external cream - hexan-1-ol, purified water

## READYinCASE Miconazole Nitrate Combination

### MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59726-989
---------------------	----------------	---------------------------	---------------

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-989-03	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	06/25/2021	

#### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	9 g
Part 2	1 BLISTER PACK	3

### Part 1 of 2

# MICONAZOLE 7

miconazole nitrate cream

## Product Information

**Item Code (Source)** NDC:59726-988

**Route of Administration** VAGINAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	10 mg in 0.5 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		9 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074164	05/01/2020	

# MICONAZOLE 3

miconazole nitrate suppository

## Product Information

Item Code (Source) NDC:59726-987

Route of Administration VAGINAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M)	MICONAZOLE NITRATE	200 mg

## Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	06/25/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	06/25/2021	

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