

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

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**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



## 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

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

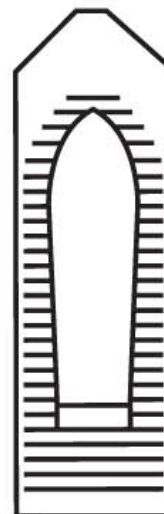
NDC 59726-989-03

# miconazole nitrate

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

vaginal antifungal  
combination pack

3 Suppositories



Actual Size



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

PLD-A672A FC007772 VC710347



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



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	

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

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

Revised: 4/2023

P & L Development, LLC