

**MICONAZOLE 3 COMBINATION PACK- miconazole nitrate  
Cardinal Health (Leader) 37205**

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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

***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 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 after each 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 room temperature 15°-30°C (59°-86°F). Avoid heat (over 30°C - 86°F)

***Inactive ingredients***

- suppository: hydrogenated vegetable oil
- external cream: benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxyglycerides, pegoxol 7 stearate, purified water

***Questions?***

**1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.**

**Principal Display Panel**

NDC 37205-589-03

LEADER®

3 DAY TREATMENT

Reusable Applicator

VAGINAL SUPPOSITORIES plus CREAM for EXTERNAL RELIEF

Compare to

Monistat® 3

active ingredient\*

Miconazole 3

Combination Pack

Miconazole Nitrate Vaginal Suppositories, USP 200 mg and

Miconazole Nitrate External Vulvar Cream, 2%

VAGINAL ANTIFUNGAL

Cures most vaginal yeast infections

Relieves associated external itching and irritation

3 Miconazole Nitrate Vaginal Suppositories, USP 200 mg plus

1 tube of Miconazole Nitrate External Vulvar Cream - NET WT 0.32 oz (9 g)



1 tube of Miconazole Nitrate External Vulvar Cream – NET WT 0.32 oz (9 g)

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

73100913G1 VC101975 Made in USA

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

DISTRIBUTED BY  
CARDINAL HEALTH  
DUBLIN, OHIO 43017  
CIN 2868503  
www.myleader.com  
1-800-200-6313



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# MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37205-589
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-589-03	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	02/02/2001	

## Quantity of Parts

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

## Part 1 of 2

### MICONAZOLE 3

miconazole nitrate suppository

#### Product Information

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	02/02/2001	

## Part 2 of 2

### MICONAZOLE 3

miconazole nitrate cream

#### Product Information

Route of Administration VAGINAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MICONAZOLE NITRATE</b> (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	10 mg in 0.5 g

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>APRICOT KERNEL OIL PEG-6 ESTERS</b> (UNII: DRG3KJZ1TJ)	
<b>PEGOXOL 7 STEARATE</b> (UNII: 3EW5AXE5X5)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### 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	ANDA074926	02/02/2001	

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**Labeler** - Cardinal Health (Leader) 37205 (097537435)

Revised: 11/2022

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