

# **MICONAZOLE 3 COMBINATION PACK- miconazole nitrate Walgreens**

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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. Throw 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 (59°-86°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

## **Package display label**

Compare to the active ingredient in Monistat® 3††

Miconazole 3

MICONAZOLE NITRATE VAGINAL SUPPOSITORIES (200 mg)

& MICONAZOLE NITRATE VAGINAL CREAM (2%)

VAGINAL ANTIFUNGAL | COMBINATION PACK | 3-DAY TREATMENT

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

3 VAGINAL SUPPOSITORIES WITH DISPOSABLE APPLICATORS PLUS EXTERNAL CREAM

NET WT OZ (G) TUBE

& SUPPOSITORIES 2.5 g EACH

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

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

## **Package label**

Walgreens



3 Vaginal Suppositories  
& Disposable Applicators



Cream for External Relief

# Miconazole 3

MICONAZOLE NITRATE VAGINAL SUPPOSITORIES (200 mg)  
& MICONAZOLE NITRATE VAGINAL CREAM (2%)  
VAGINAL ANTIFUNGAL | COMBINATION PACK | 3-DAY TREATMENT

NDC 0383-9089-03

Walgreens



Compare to the active  
ingredient in Monistat® 3<sup>®</sup>

# Miconazole 3

MICONAZOLE NITRATE VAGINAL SUPPOSITORIES (200 mg)  
& MICONAZOLE NITRATE VAGINAL CREAM (2%)  
VAGINAL ANTIFUNGAL | COMBINATION PACK | 3-DAY TREATMENT

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

3 VAGINAL SUPPOSITORIES WITH  
DISPOSABLE APPLICATORS PLUS EXTERNAL CREAM

NET WT 0.32 OZ (9 g) TUBE  
& 3 SUPPOSITORIES 2.5 g EACH

DISTRIBUTED BY: WALGREEN CO.  
200 WILMOT RD., DEERFIELD, IL 60015

Walgreens

**100%** SATISFACTION  
GUARANTEED

walgreens.com

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ITEM 789176 W10141-1219-0



Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands. 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

**Inactive ingredients**  
 external cream: benzoic acid, butyated hydroxyanisole, mineral oil, cetyl polyoxyglycol ether, pectin, purified water  
 suppository: hydrogenated vegetable oil

**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)

**Directions**  
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 ■ 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, as needed.  
 ■ children under 12 years of age: ask a doctor

**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

**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

**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.

**Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.**

**Warnings**  
 For vaginal use only  
 ■ Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur.  
 ■ Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.  
 ■ Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.

**Uses**  
 ■ treats vaginal yeast infections ■ relieves external itching and irritation due to a vaginal yeast infection

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

**Purpose**  
 Vaginal antifungal  
 Vaginal antifungal

**WALGREENS Vaginal Suppositories with Disposable Applicators plus External Cream**

**MICONAZOLE 3 COMBINATION PACK**

miconazole nitrate kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-9089
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9089-03	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	06/10/2022	

## 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

Item Code (Source)	NDC:0363-9093
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	06/10/2022	

## Part 2 of 2

### MICONAZOLE 3

miconazole nitrate cream

**Product Information****Item Code (Source)** NDC:0363-9092**Route of Administration** VAGINAL**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<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**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1		9 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA074926	06/10/2022	

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ANDA	ANDA074926	06/10/2022	

**Labeler** - Walgreens (008965063)