

**CVS MICONAZOLE 1 COMBINATION PACK- miconazole nitrate  
CVS PHARMACY, INC**

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**CVS MICONAZOLE 1 COMBINATION PACK 51316-093**

**Drug Facts**

***Active ingredients***

Miconazole nitrate 1200 mg (in vaginal insert)

Miconazole nitrate 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
- 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 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:
  - **vaginal insert:** with the applicator, place the vaginal insert into the vagina. Throw away applicator.
  - **external cream:** squeeze a small amount of cream onto your fingertip. 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 **printed** sealed pouch is torn, open or incompletely sealed
- do not use if seal over tube opening has been punctured
- do not purchase if carton is open
- store at 20°-25°C (68°-77°F)
- this is a 1-dose treatment. Most women do not get complete relief of their symptoms in just 1 day. Most women get some improvement in 1 day and complete relief by 7 days.

### **Inactive ingredients**

**vaginal insert:** gelatin, glycerin, lecithin, mineral oil, titanium dioxide, white petrolatum

**external cream:** benzoic acid, cetyl alcohol, isopropyl myristate, polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol

### **Questions?**

If you have any questions or comments, please call 1-877-666-4782

## PRINCIPAL DISPLAY PANEL

### 1-Day Treatment

#### Miconazole 1

Miconazole Nitrate Vaginal Insert **1200 mg**

& Miconazole Nitrate Vaginal Cream **2%**

Combination Pack

Daytime or Nighttime

Vaginal antifungal, Yeast infection relief

Net WT 0.32oz (9g) tube

1 Vaginal Softgel Insert + Applicator

**Drug Facts**

**Active ingredients**  
Miconazole nitrate 1200 mg (in vaginal insert) Vaginal antifungal  
Miconazole nitrate 2% (external cream) Vaginal antifungal

**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 food-avoiding vaginal discharge. You may have a more serious condition.  
● vaginal yeast infections often (such as once a month or 2 to 3 times a month). 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 fever, abdominal pain, fever, chills, nausea, vomiting, or food-avoiding 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 booklet for complete directions and information  
● adults and children 12 years of age and over:  
● **vaginal insert:** with the applicator, place the vaginal insert into the vagina. Throw away applicator.  
● **external cream:** squeeze a small amount of cream onto your fingertip. 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 printed sealed pouch is torn, open or incompletely sealed  
● do not use if seal over the opening has been punctured  
● do not purchase if carton is open  
● store at 20°-25°C (68°-77°F)

**Drug Facts (continued)**  
● this is a 1-day treatment. Most women do not get complete relief of these symptoms in just 1 day. Most women get some improvement in 1 day and complete relief by 7 days.  
**Inactive ingredients**  
● vaginal insert: gelatin, glycerin, lecithin, mineral oil, titanium dioxide, white petrolatum  
● external cream: benzoic acid, cetyl alcohol, isopropyl myristate, polyorbate III, potassium hydroxide, propylene glycol, purified water, stearyl alcohol

**Questions?** ● if you have any questions or comments, please call 1-877-666-4782

**TAMPER-EVIDENT UNIT**  
DO NOT USE IF PRINTED SEALED POUCH IS TORN, OPEN OR INCOMPLETELY SEALED.

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**CVS**  
1 Vaginal Softgel Insert With 1 Applicator  
1 Tube of External Cream  
**ONE-DAY TREATMENT**

**1-Day Treatment**  
**MICONAZOLE 1**  
Miconazole Nitrate Vaginal Insert  
1200 mg & Miconazole Nitrate  
Vaginal Cream 2%  
Combination Pack

Compare to Monistat® 1 active ingredients\*

Daytime or Nighttime

Vaginal Antifungal, Yeast Infection Relief | Cures Most Vaginal Yeast Infections | Relieves Associated External Itching & Irritation | Stays In Place

NET WT 0.32 OZ (9 g) TUBE  
1 VAGINAL SOFTGEL INSERT + APPLICATOR

**1-Day Treatment**  
**MICONAZOLE 1**

## CVS MICONAZOLE 1 COMBINATION PACK

miconazole nitrate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-093
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:51316-093-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/30/2022
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### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 POUCH	1
Part 2	1 TUBE	9 g

### Part 1 of 2

### MICONAZOLE NITRATE

miconazole nitrate suppository

### Product Information

Item Code (Source)	NDC:51316-094
Route of Administration	VAGINAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	1200 mg

### Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1D156QDM62)	
MINERAL OIL (UNII: T5L8T28FGP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PETROLATUM (UNII: 4T6H12BN9U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-094-01	1 in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021308	01/30/2022	

## Part 2 of 2

### MICONAZOLE NITRATE

miconazole nitrate cream

#### Product Information

Item Code (Source)	NDC:51316-095
Route of Administration	VAGINAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	20 mg in 1 g

#### Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-095-01	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
NDA	NDA021308	01/30/2022	

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021308	01/30/2022	

**Labeler** - CVS PHARMACY, INC (062312574)

Revised: 3/2026

CVS PHARMACY, INC