

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

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**Miconazole 1 Combination Pack**

**Drug Facts**

***Active ingredients***

***Purpose***

Miconazole nitrate 1200 mg (in vaginal insert)                      Vaginal antifungal  
Miconazole nitrate 2% (external cream)                      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 applicator away after use.
  - **external cream:** squeeze a small amount of cream onto your fingertip. Apply the cream onto the itchy, irritated skin outside the vagina (vulva). 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 or sealed vaginal insert blister 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?**

call toll-free **877-666-4782**

## PRINCIPAL DISPLAY PANEL

### Miconazole 1

Miconazole Nitrate Vaginal Insert (1200 mg)

Miconazole Nitrate Cream (2%)

VAGINAL ANTIFUNGAL | Yeast infection relief

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

Net Wt. 0.32oz (9g) tube

1 Vaginal Softgel Insert + Applicator

**Daytime or Nighttime**

- Stays in place
- Combination pack

TREAT THE INFECTION  
1 Vaginal softgel insert  
& 1 Applicator

RELIEVE ITCHING  
& IRRITATION  
1 Tube of external cream

♥CVSHealth.

Combination Pack  
**Miconazole 1**  
MICONAZOLE NITRATE VAGINAL INSERT (1200 mg)  
MICONAZOLE NITRATE CREAM (2%)  
Vaginal antifungal • Yeast infection relief

♥CVSHealth.

Compare to the active ingredients in Monistat®1\*

1-Day Treatment; Day or Night

Combination Pack  
**Miconazole 1**  
MICONAZOLE NITRATE VAGINAL INSERT (1200 mg)  
MICONAZOLE NITRATE CREAM (2%)  
Vaginal antifungal • Yeast infection relief

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

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

\*This product is not manufactured or distributed by Insight Pharmaceuticals, LLC, distributor of Monistat®1.

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CVS.com® 1-800-SHOP  
V-30139 MPUS011101



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**Drug Facts** (continued)

**Active ingredients**  
Miconazole nitrate 1200 mg (in vaginal insert)  
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**  
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**  
Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).  
Do not have vaginal intercourse  
■ if you do not get complete relief or irritation may occur  
■ 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.

**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 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 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 80, potassium hydroxide, propylene glycol, purified water, stearyl alcohol.

**Questions?** If you have any questions or comments, please call 1-877-665-4782.

CVS Health

# MICONAZOLE 1 COMBINATION PACK

miconazole nitrate kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-005
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-005-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/30/2022	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
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<b>Part 1</b>	1 POUCH	1
<b>Part 2</b>	1 TUBE	9 g

## Part 1 of 2

### MICONAZOLE NITRATE

miconazole nitrate suppository

#### 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	1200 mg

#### Inactive Ingredients

Ingredient Name	Strength
<b>Gelatin</b> (UNII: 2G86QN327L)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Mineral Oil</b> (UNII: T5L8T28FGP)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	
<b>Petrolatum</b> (UNII: 4T6H12BN9U)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	NDA020670	01/30/2022	

## Part 2 of 2

### MICONAZOLE NITRATE

miconazole nitrate cream

## 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	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: 059QF0K00R)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	

## 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
NDA	NDA020670	01/30/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	01/30/2022	

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

**Registrant** - Insight Pharmaceuticals (055665422)