

**MONISTAT 3 3 DAY- miconazole nitrate cream**  
**Insight Pharmaceuticals LLC**

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**Monistat 3 3 Day 63736-015**

**Drug Facts**

**Active ingredient**

Miconazole nitrate 4%

**Purpose**

Vaginal antifungal

**Use**

- treats vaginal yeast infections

**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 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 disease (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 after 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:
  - insert 1 applicatorful into the vagina at bedtime for 3 nights in a row. Throw applicator away after use.
- children under 12 years of age: ask a doctor

### **Other information**

- do not use if **printed** applicator wrapper is torn, open or incompletely sealed
- do not purchase if carton is open
- store at 20° - 25°C (68° - 77°F)

### **Inactive ingredients**

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**

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## **PRINCIPAL DISPLAY PANEL - 5 g Tube Carton**

### **3-DAY TREATMENT**

#### ***Prefilled Cream Applicator***

#### **MONISTAT® 3**

Miconazole Nitrate Vaginal Cream (4%)- Vaginal Antifungal

3 Prefilled Applicators Net Wt. 0.18 oz. (5g) each

3-DAY TREATMENT

**Prefilled Cream Applicator**

3 Ready-to-Use Prefilled Applicators

**MONISTAT<sup>®</sup> 3**  
Miconazole Nitrate Vaginal Cream (4%) – Vaginal Antifungal

**TAMPER-EVIDENT UNIT DO NOT USE IF PRINTED APPLICATOR WRAPPER IS TORN, OPENED OR INCOMPLETELY SEALED**

**MONISTAT<sup>®</sup> 3**  
Miconazole Nitrate Vaginal Cream (4%) – Vaginal Antifungal

✓ CURES most vaginal YEAST INFECTIONS

3 Prefilled Applicators Net Wt. 0.18 oz (5 g) each

**MONISTAT<sup>®</sup> 3**  
Miconazole Nitrate Vaginal Cream (4%) – Vaginal Antifungal

<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Miconazole nitrate 4%</p> <p><b>Purpose</b> Vaginal antifungal</p> <p><b>Use</b> • treats vaginal yeast infections</p> <p><b>Warnings</b> 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 • fever, 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.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>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).</li> <li>do not have vaginal intercourse</li> <li>mild increase in vaginal burning, itching or irritation may occur</li> <li>if you do not get complete relief ask a doctor before using another product</li> </ul> <p><b>Stop use and ask a doctor if:</b></p> <ul style="list-style-type: none"> <li>symptoms do not get better in 3 days</li> <li>symptoms last more than 7 days</li> <li>you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge</li> </ul> <p><b>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If overserved, get medical help or contact a Poison Control Center right away.</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>before using this product read the enclosed consumer information leaflet for complete directions and information.</li> <li>adults and children 12 years of age and over:             <ul style="list-style-type: none"> <li>insert 1 applicatorful into the vagina at bedtime for 3 nights in a row.</li> <li>Throw applicator away after use.</li> </ul> </li> <li>children under 12 years of age: ask a doctor.</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>do not use if printed applicator wrapper is torn, open or incompletely sealed</li> <li>do not purchase if carton is open</li> <li>store at 20°–25°C (68°–77°F)</li> </ul> <p><b>Inactive ingredients</b> benzoic acid, cetyl alcohol, isopropyl myristate, polysorbate 80, potassium hydroxide, propylene glycol, purified water, stearyl alcohol</p> <p><b>Questions?</b> If you have any questions or comments, please call 1-877-666-4782.</p>
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PRINCIPAL DISPLAY PANEL

3 DAY TREATMENT • CREAM

MONISTAT<sup>®</sup> 3

Miconazole Nitrate Vaginal Cream (4%)

## Vaginal Antifungal

Net Wt. 0.9 oz. (25g) Tube + 1 Reusable Applicator



# MONISTAT<sup>®</sup> 3

Miconazole Nitrate Vaginal Cream (4%) — Vaginal Antifungal

## Drug Facts

### Active ingredient

Miconazole nitrate 4% \_\_\_\_\_ Vaginal antifungal

### Purpose

Vaginal antifungal

### Use

■ treats vaginal yeast infections

### Warnings

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## MONISTAT 3 3 DAY

miconazole nitrate cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-015
Route of Administration	VAGINAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	40 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)	

<b>Potassium Hydroxide</b> (UNII: WZH3C48M4T)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Stearyl Alcohol</b> (UNII: 2KR89I4H1Y)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-015-18	3 in 1 CARTON	03/30/1998	
1		5 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		
2	NDC:63736-015-25	1 in 1 CARTON	03/30/1998	
2		25 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020827	03/30/1998	

**Labeler** - Insight Pharmaceuticals LLC (055665422)

Revised: 8/2023

Insight Pharmaceuticals LLC