

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

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**Monistat 3 Cure Itch Relief\_Suppository-Cream**

**Drug Facts**

**Active ingredients**

**Purpose**

Miconazole nitrate (200 mg in each suppository).....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:
  - **suppositories:** insert 1 suppository into the vagina at bedtime for three nights in a row. 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. 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** suppository blisters are 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)

**Inactive ingredients**

**suppository:** hydrogenated vegetable oil base

**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**

MONISTAT® 3

COMBINATION PACK

Miconazole Nitrate Vaginal Suppositories (200 mg) and Miconazole Nitrate Vaginal Cream (2%)

VAGINAL ANTIFUNGAL

3 Suppositories Net Wt. 2.5 g each \_ 0.32 oz (9 g) Tube



**3-DAY TREATMENT**  
COMBINATION PACK

**Suppository** + **plus External Cream for Itch Relief**

Vaginal Suppositories with 3 Applicators

**MONISTAT<sup>®</sup> 3**  
COMBINATION PACK  
Miconazole Nitrate Vaginal Suppositories (200 mg) and Miconazole Nitrate Vaginal Cream (2%) — Vaginal Antifungal

**TAMPER-EVIDENT UNIT**  
DO NOT USE IF PRINTED SUPPOSITORY BLISTERS OR SEAL OVER TUBE ARE TORN, OPENED OR INCOMPLETELY SEALED

**MONISTAT<sup>®</sup> 3**  
COMBINATION PACK  
Miconazole Nitrate Vaginal Suppositories (200 mg) and Miconazole Nitrate Vaginal Cream (2%) — Vaginal Antifungal

- ✓ CURES most vaginal YEAST INFECTIONS
- ✓ Relieves associated external itching and irritation

**3 Suppositories Net Wt. 2.5 g each + 0.32 oz (9 g) Tube**

# MONISTAT 3

COMBINATION PACK

Miconazole Nitrate Vaginal Suppositories (200 mg) and  
Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

<b>Drug Facts</b> <b>Active ingredients</b> Miconazole nitrate (200 mg in each suppository)....Vaginal antifungal Miconazole nitrate 2% (external cream).....Vaginal antifungal		<b>Purpose</b> Vaginal antifungal Vaginal antifungal	
<b>Uses</b> <ul style="list-style-type: none"> <li>treats vaginal yeast infections</li> <li>relieves external itching and irritation due to a vaginal yeast infection</li> </ul>		<b>Drug Facts (continued)</b> Stop use and ask a doctor if: <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> 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.	
<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: <ul style="list-style-type: none"> <li>vaginal itching and discomfort for the first time</li> <li>lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.</li> <li>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.</li> <li>been exposed to the human immunodeficiency virus (HIV) that causes AIDS</li> </ul> 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: <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>		<b>Directions</b> <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><b>suppositories:</b> insert 1 suppository into the vagina at bedtime for three nights in a row. Throw applicator away after use.</li> <li><b>external cream:</b> 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.</li> </ul> </li> <li>children under 12 years of age: ask a doctor.</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>do not use if <b>printed</b> suppository blisters are torn, open or incompletely sealed</li> <li>do not use if seal over tube opening has been punctured</li> <li>do not purchase if carton is open</li> <li>store at 20°-25°C (68°-77°F)</li> </ul>		<b>Inactive ingredients</b> suppository: hydrogenated vegetable oil base external cream: benzoic acid, cetyl alcohol, isopropyl myristate, polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol	
<b>Questions?</b> If you have any questions or comments, please call 1-877-666-4782.			

## MONISTAT 3

miconazole nitrate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63736-017
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-017-03	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	04/16/1996	

### 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

### MONISTAT 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)	

#### Product Characteristics

Color	white (off-white to white)	Score	
Shape	BULLET	Size	
Flavor		Imprint Code	
Contains			

#### 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
NDA	NDA020670	04/16/1996	

## Part 2 of 2

### MONISTAT 3

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	10 mg in 0.5 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		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	04/16/1996	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	04/16/1996	

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