

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

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**MONISTAT 3 Combination Pack - prefilled app and cream**

**DRUG FACTS**

*Active ingredients*

*Purpose*

Miconazole nitrate 4% (200 mg in each applicator)      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:
- **applicators:** insert 1 suppository into the vagina at bedtime for 3 nights in a row. Throw away applicator 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 wrapper 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)

**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**

**PRINCIPAL DISPLAY PANEL**

**- Kit Carton**

**MONISTAT® 3**

**COMBINATION PACK**

Miconazole Nitrate Vaginal Cream (4%) and Miconazole Nitrate Cream (2%)  
(Miconazole Nitrate 200 mg per applicator plus 2% external vulvar cream)

**VAGINAL ANTIFUNGAL**

**3 PREFILLED APPLICATORS**

Net Wt. 0.18 oz. (5g) each applicator

plus External Cream for Itch Relief

+0.32 oz. (9g) tube

3-DAY  
TREATMENT  
COMBINATION PACK

Prefilled Cream



3 Ready-to-Use  
Prefilled Applicators

plus External Cream  
for Itch Relief

**MONISTAT<sup>®</sup>**  
COMBINATION PACK  
Miconazole Nitrate Vaginal Cream (4%) and Miconazole Nitrate Vaginal Cream (2%)  
VAGINAL ANTIFUNGAL

3

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

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**MONISTAT<sup>®</sup>**  
COMBINATION PACK  
Miconazole Nitrate Vaginal Cream (4%) and Miconazole Nitrate Vaginal Cream (2%)  
(Miconazole Nitrate 200 mg per applicator plus 2% external vulvar cream)  
VAGINAL ANTIFUNGAL

3

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

3 PREFILLED APPLICATORS  
plus External Cream for Itch Relief

Net Wt. 0.18 oz (5g) each applicator  
+ 0.32 oz (9g) Tube



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

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

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NON-VARNISH AREA



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<p><b>Drug Facts</b> (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <p>Before using this product read the enclosed consumer information for complete directions and information.</p> <p>• Wash and dry your hands before and after use.</p> <p>• Apply one applicator 12 years of age and older at bedtime for 3 nights in a row. Insert applicator away from you.</p> <p>• External cream requires a small amount of cream per use. Apply the cream with the help of the applicator.</p> <p>• Use 2 times daily for up to 7 days, as needed.</p> <p>• Children under 12 years of age, ask a doctor.</p> <p><b>Other Information</b></p> <p>• Do not use if printed applicator wrapper is torn, open or incompletely sealed.</p> <p>• Do not use if seal over the opening has been punctured.</p> <p>• Do not put in your mouth.</p> <p>• Do not use if stored over 2 years from the date of manufacture.</p> <p>• Store at 20°-25°C (68°-77°F).</p> <p><b>Active Ingredients</b></p> <p>Miconazole Nitrate 200 mg per applicator plus 2% external vulvar cream.</p> <p><b>Questions? If you have any questions or comments, please call 1-877-666-4782.</b></p>	<p><b>Drug Facts</b></p> <p><b>Active Ingredient</b></p> <p>Miconazole Nitrate 4% (200 mg in each applicator), vaginal antifungal (Miconazole Nitrate 2% external cream)</p> <p><b>Purpose</b></p> <p>Relieves external itching and irritation due to a vaginal yeast infection.</p> <p><b>Uses</b></p> <p>• Treats vaginal yeast infections.</p> <p>• Relieves external itching and irritation due to a vaginal yeast infection.</p> <p><b>Warnings</b></p> <p>Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.</p> <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> <li>• vaginal itching and discomfort by the first time</li> <li>• vaginal itching or discharge that is recurrent, severe, or persistent</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> </ul> <p>vaginal yeast infections often last as long as a month or 2 to 3 months.</p> <p>• You could be pregnant or have a chance of becoming pregnant. Tell your doctor if you are pregnant, planning to get pregnant, or have a chance of getting pregnant.</p> <p>• Tell your doctor if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur.</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. Containers and applicators may be damaged and left to dry out. <li>• do not have vaginal intercourse.</li> <li>• do not 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> </li></ul> <p><b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b></p>
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MONISTAT<sup>®</sup> 3  
COMBINATION PACK  
VAGINAL ANTIFUNGAL

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COMBINATION PACK  
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**MONISTAT 3 COMBINATION PACK**

miconazole nitrate kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63736-010
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-010-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	12/10/2009	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 APPLICATOR	3 g
Part 2	1 TUBE	9 g

**Part 1 of 2****MONISTAT 3**

miconazole nitrate cream

**Product Information**

<b>Route of Administration</b>	VAGINAL
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**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)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	

Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 g in 1 APPLICATOR; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	12/10/2009	

### Part 2 of 2

**MICONAZOLE NITRATE**  
miconazole nitrate cream

### Product Information

Route of Administration	VAGINAL
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### 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	12/10/2009	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	12/10/2009	

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

Revised: 4/2020

Insight Pharmaceuticals LLC