

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

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**MONISTAT 3 COMBINATION PACK 3 OVULE INSERTS**

**Drug Facts**

**Active ingredients**

Miconazole nitrate (200 mg in each 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 a disposable applicator, place the insert into the vagina at bedtime. 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 sealed pouches containing vaginal inserts 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**

**vaginal insert:** gelatin, glycerin, hydrogenated vegetable oil base, titanium dioxide

**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 Inserts (200 mg) and Miconazole Nitrate Vaginal Cream (2%)

VAGINAL ANTIFUNGAL

**3 OVULE® Inserts** with 3 Applicators (Net Wt. 3 OVULE® Inserts)

plus External Cream for Itch Relief (0.32 oz (9 g) Tube

3-DAY  
TREATMENT  
COMBINATION PACK

Ovule®

3 Ovule® Inserts

Plus External Cream  
for Itch Relief

**MONISTAT®**  
COMBINATION PACK

Miconazole Nitrate Vaginal Inserts (200 mg)  
and Miconazole Nitrate Vaginal Cream (2%)  
VAGINAL ANTIFUNGAL

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

**MONISTAT®**  
COMBINATION PACK

Miconazole Nitrate Vaginal Inserts (200 mg)  
and Miconazole Nitrate Vaginal Cream (2%)  
VAGINAL ANTIFUNGAL

3

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

3 OVULE® Inserts with 3 Applicators  
plus External Cream for Itch Relief

Net Wt. 3 OVULE® Inserts  
+ 0.32 oz (9g) Tube



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

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questions or  
comments, please call  
1-877-MONISTAT  
(1-877-666-4782)

<p><b>Drug Facts</b> (continued)</p> <p><b>Stop use and ask a doctor:</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 have abdominal pain, fever, chills, nausea, vomiting, or food poisoning</li> </ul> <p><b>Keep out of reach of children.</b> 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 leaflet for complete directions and information.</p> <p>• adults and children 12 years of age and over</p> <p>• vaginal insert with a disposable applicator: place the insert into the vagina at bedtime. Throw applicator away after use.</p> <p>• external cream: squeeze a small amount of cream onto your fingertip. Apply the cream onto the clitoris, labia, and inside the vagina. 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> <ul style="list-style-type: none"> <li>• do not use if printed sealed pouches containing vaginal inserts are torn, open or incompletely sealed</li> <li>• do not use if seal over tube opening has been punctured</li> <li>• do not use if seal over tube opening is open</li> <li>• store at 20°-25°C (68°-77°F)</li> </ul> <p><b>Inactive ingredients</b></p> <p>vaginal insert: glycerin, polyethylene glycol, hydroxyethylcellulose, hydroxypropyl methylcellulose, polyethylene glycol, purified water, xanthan gum</p> <p>external cream: benzocaine, cetostearyl alcohol, hydroxypropyl methylcellulose, polyethylene glycol, purified water, xanthan gum</p> <p><b>Questions? If you have any questions or comments, please call 1-877-666-4782.</b></p>	<p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>• For vaginal use only</li> <li>• Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.</li> <li>• Ask a doctor before use if you have: <ul style="list-style-type: none"> <li>• vaginal itching and discomfort the first time</li> <li>• brown discharge, back or abdominal pain, fever, chills, nausea,</li> <li>• vomiting, or food poisoning</li> </ul> </li> <li>• vaginal yeast infections often recur as often as once a month or 2 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> <li>• Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur.</li> <li>• When using the 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 disease (STD).</li> <li>• do not have vaginal intercourse</li> <li>• mild increase in vaginal burning, itching or irritation may occur if you do not get complete relief; ask a doctor before using another product</li> </ul> </li> </ul> <p><b>Uses</b></p> <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> <p><b>Active ingredients</b></p> <p>Miconazole nitrate 2% (miconazole nitrate). Vaginal antifungal.</p> <p><b>Purpose</b></p> <p>• prevents or treats vaginal yeast infections</p>
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**MONISTAT®**  
COMBINATION PACK

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# MONISTAT 3 COMBINATION PACK 3 OVULE INSERTS

miconazole nitrate kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63736-019
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-019-03	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 KIT	3
Part 2	1 TUBE	9 g

## Part 1 of 2

### MICONAZOLE NITRATE

miconazole nitrate suppository

## 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	200 mg

## Inactive Ingredients

Ingredient Name	Strength
Gelatin (UNII: 2G86QN327L)	
Glycerin (UNII: PDC6A3C0OX)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3 in 1 KIT; Type 1: Convenience Kit of Co-Package		

## Marketing Information

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

## 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	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: 2KR89I4HIY)	

## 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
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NDA	NDA020670	04/16/1996	
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**Labeler** - Insight Pharmaceuticals LLC (055665422)

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Insight Pharmaceuticals LLC