

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

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**MONISTAT 3 COMBINATION PACK\_Ovule inserts-tube\_63736-019-03**

**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 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** 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** Net Wt. 2.5 g each +

0.32 oz (9 g) Tube

**3-DAY TREATMENT COMBINATION PACK**

**Ovule®**

3 Ovule® Inserts + Plus External Cream for Itch Relief

**MONISTAT® 3**  
COMBINATION PACK  
Miconazole Nitrate Vaginal Insert (200 mg) and Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

**MONISTAT® 3**  
COMBINATION PACK  
Miconazole Nitrate Vaginal Insert (200 mg) and Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

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

3 OVULE® Inserts Net Wt. 2.5 g each + 0.32 oz (9 g) Tube

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

**MONISTAT® 3**  
COMBINATION PACK  
Miconazole Nitrate Vaginal Insert (200 mg) and Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

<p><b>Drug Facts</b></p> <p><b>Active ingredients</b> Miconazole nitrate (200 mg in each vaginal insert). Vaginal antifungal. Miconazole nitrate 2% (external cream). Vaginal antifungal.</p> <p><b>Purpose</b> Vaginal antifungal.</p> <p><b>Uses</b> • treats vaginal yeast infections • relieves external itching and irritation due to a vaginal yeast infection</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 • lower abdominal, back or shoulder pain, fever, chills, sores, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition. • vaginal yeast infections often (such 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. • 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>When using this product</b> • 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.</p>		<p><b>Drug Facts (continued)</b></p> <p>Stay out of reach of children. • symptoms do not get better in 3 days • symptoms last more than 7 days • you get a rash or hives, abdominal pain, fever, chills, sores, vomiting, or foul-smelling vaginal discharge</p> <p>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.</p> <p><b>Directions</b> • before using this product read the enclosed consumer information leaflet for complete directions and information. • adults and children 12 years of age and over: • <b>vaginal insert:</b> with a disposable applicator, place the insert into the vagina at bedtime for three nights in a row. Throw applicator away after use. • <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. • children under 12 years of age: ask a doctor.</p> <p><b>Other information</b> • 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)</p> <p><b>Inactive ingredients</b> <b>vaginal insert:</b> gelatin, glycerin, hydrogenated vegetable oil base, titanium dioxide <b>external cream:</b> benzoic acid, cetyl alcohol, isopropyl myristate, polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol</p> <p><b>Questions?</b> If you have any questions or comments, please call 1-877-605-4762.</p>
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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
<b>Miconazole Nitrate</b> (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>Gelatin</b> (UNII: 2G86QN327L)	
<b>Glycerin</b> (UNII: PDC6A3C00X)	
<b>Titanium Dioxide</b> (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	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
NDA	NDA020670	04/16/1996	

## 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: 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)

Revised: 4/2024

Insight Pharmaceuticals LLC