

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

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**MONISTAT 3 Combination Pack - 63736-010**

**DRUG FACTS**

***Active ingredients***

Miconazole nitrate 4%  
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:
- **applicators:** insert 1 applicatorful 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** applicator 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)
- Keep this carton for future reference. It contains important information.

***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%) - Vaginal Antifungal

**3 PREFILLED APPLICATORS**

Net Wt. 0.18 oz. (5g) +0.32 oz. (9g) tube



**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	3 APPLICATOR	15 g
Part 2	1 TUBE	9 g

## Part 1 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	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: 2KR89I4H1Y)	

#### Product Characteristics

Color	white	Score	
Shape		Size	
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	NDA021261	12/10/2009	

## 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
<b>Miconazole Nitrate</b> (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	10 mg in 0.5 g

#### Inactive Ingredients

Ingredient Name	Strength
<b>Benzoic Acid</b> (UNII: 8SKN0B0MIM)	
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
<b>Isopropyl Myristate</b> (UNII: 0RE8K4LNJS)	
<b>Polysorbate 60</b> (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		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	NDA021261	12/10/2009	

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NDA	NDA021261	12/10/2009	

