

**MONISTAT 7 COMBINATION PACK 7-DAY PRE-FILLED APPLICATORS- miconazole nitrate**

**Insight Pharmaceuticals LLC**

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**Monistat 7 Cure Itch Relief - PreFilledApps-Cream**

**MONISTAT 7 COMBINATION PACK 7-DAY PRE-FILLED APPLICATORS- miconazole nitrate**

**Insight Pharmaceuticals**

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**MONISTAT<sup>®</sup> 7 Combination Pack**

***Drug Facts***

***Active ingredient***

Miconazole nitrate (100 mg in each applicator)

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 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 disease (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 after 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 7 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 (vulva). 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 not use if seal over tube opening has been punctured
- do not purchase if carton is open
- store at 20° - 25°C (68° to 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® 7**

**C O M B I N A T I O N P A C K**

Miconazole Nitrate Vaginal Cream (2%) and Miconazole Nitrate Vaginal Cream (2%)

**VAGINAL ANTIFUNGAL**

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

#### **VAGINAL CREAM**

with 7 Disposable Applicators

plus External Cream for Itch Relief

Net Wt. 1.59 oz (45g)

+ 0.32 oz (9g) Tube

7-DAY  
TREATMENT  
COMBINATION PACK

***Cream***

7 Disposable Applicators plus External Cream for Itch Relief

TAMPER-EVIDENT UNIT  
DO NOT USE IF SEAL OVER TYPE  
HAS BEEN PUNCTURED.

If you have any  
questions or  
comments, please call

1-877-MONISTAT  
(1-877-666-4782)

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**COMBINATION PACK**

Miconazole Nitrate Vaginal Cream (2%) and Miconazole Nitrate Cream (2%)  
VAGINAL ANTIFUNGAL

**VAGINAL CREAM**

<b>with</b> 7 Disposable Applicators	Net Wt. 1.59 oz. (45g)
<b>plus</b> External Cream for Itch Relief	+ 0.32 oz. (9g) tube



**Drug Facts**

**Active Ingredients**  
Miconazole nitrate 2% (100 mg in each applicator).....Vaginal antifungal  
Miconazole nitrate 2% (external cream).....Vaginal antifungal

**Purpose**  
Vaginal antifungal

**Uses**  

- treats vaginal yeast infections
- relieves external itching and irritation due to a vaginal yeast infection

**Warnings**  
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 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

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**When using this product**  

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- if you do not get complete relief ask a doctor before using another product

**Drug Facts (continued)**  
**Stop use and ask a doctor if**  

- symptoms do not get better in 3 days
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**Directions**  
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  - 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 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 80, potassium hydroxide, propylene glycol, purified water, stearyl alcohol

**Questions?** If you have any questions or comments, please call 1-877-666-4782.

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DO NOT USE IF SEAL OVER TUBE  
 HAS BEEN PUNCTURED.

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

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MONISTAT 7 COMBINATION PACK 7-DAY PRE-FILLED APPLICATORS				
miconazole nitrate kit				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-023	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-023-15	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	04/23/2020	
Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	7 TUBE, WITH APPLICATOR	35 g		
Part 2	1 TUBE	9 g		
Part 1 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: 2KR89I4HIY)	

### Packaging

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

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017450	04/26/1993	

### Part 2 of 2

### MICONAZOLE NITRATE

miconazole nitrate cream

### Product Information

Route of Administration VAGINAL

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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: 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	NDA017450	04/26/1993	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017450	04/23/2020	

**Labeler** - Insight Pharmaceuticals LLC (055665422)**Registrant** - Apex International Mfg., Inc. (079110793)**Establishment**

Name	Address	ID/FEI	Business Operations
Apex International Mfg., Inc.		079110793	manufacture(63736-023)