

**MONISTAT 7 WITH REUSABLE APPLICATOR- miconazole nitrate cream**  
**Insight Pharmaceuticals LLC**

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

**Drug Facts**

**Active ingredients**

**Purpose**

Miconazole nitrate 2% .....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

**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, committing, 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:
  - **applicator:** Insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Wash applicator after use.
  - use the same tube of cream if you have itching and irritation on the skin outside the vagina. 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 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® 7  
Miconazole Nitrate Vaginal Cream (2%)

Vaginal Antifungal

1 Reusable Applicator

Net Wt. 1.59 oz. (45g) Tube



# MONISTAT

Miconazole Nitrate Vaginal Cream (2%)  
(Miconazole Nitrate 100 mg per applicator)  
VAGINAL ANTIFUNGAL

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

# MONISTAT

Miconazole Nitrate Vaginal Cream (2%)  
(Miconazole Nitrate 100 mg per applicator)  
VAGINAL ANTIFUNGAL

# 7

# 7

MONISTAT  
Miconazole Nitrate Vaginal Cream (2%)  
(Miconazole Nitrate 100 mg per applicator)  
VAGINAL ANTIFUNGAL

OPEN HERE

Exp  
Lot

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

VAGINAL CREAM  
with 1 Reusable Applicator

Net Wt. 1.59 oz (45g) Tube



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

Dist. by Insight Pharmaceuticals LLC, Tarrytown, NY 10591  
A Prestige Consumer Healthcare company  
©2019 Trade dress is owned by Insight Pharmaceuticals LLC  
All rights reserved. MNU5022904

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

<p><b>Drug Facts</b> (continued)</p> <p><b>Active ingredients</b> Miconazole nitrate 2% (100 mg in each applicator). 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 ever 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 • fever, 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 2 to 3 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.</p> <p><b>Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur.</b></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>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: • applicator: insert 1 applicator into the vagina at bedtime for 7 nights in a row. Wash applicator after use. • use the same tube of cream if you have itching and irritation on the skin outside the vagina. Squeeze a small amount of cream into your fingertip. Apply the cream onto the itchy, irritated skin. • children under 12 years of age: ask a doctor.</p> <p><b>Other information</b> • 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).</p> <p><b>Inactive ingredients</b> benzoic acid, cetyl alcohol, isopropyl myristate, potassium bitartrate, potassium hydroxide, propylene glycol, purified water, stearic alcohol.</p> <p><b>Questions?</b> If you have any questions or comments, please call 1-877-666-4782.</p>
---	--

MONISTAT 7 WITH REUSABLE APPLICATOR  
miconazole nitrate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63736-025
<b>Route of Administration</b>	VAGINAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	20 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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	NDC:63736-025-15	1 in 1 CARTON	04/26/1993	
1		45 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

**Marketing Information**

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

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

Revised: 4/2020

Insight Pharmaceuticals LLC