

MONISTAT 7 COMBINATION PACK TRIPLE ACTION- miconazole nitrate
Insight Pharmaceuticals

Monistat 7 Combination Pack Triple Action

Drug Facts

Active ingredients	Purpose
Miconazole nitrate 2% (100 mg in each applicatorful)	Vaginal antifungal
Miconazole nitrate 2% (external cream)	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 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 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?

call toll-free **877-666-4782**

Distributed by: INSIGHT Pharmaceuticals, LLC., Treviso, PA 19053

PRINCIPAL DISPLAY PANEL - Kit Carton

7 DAY TREATMENT • CREAM

MONISTAT® 7

Miconazole Nitrate Vaginal Cream (2%) and Miconazole Nitrate Cream (2%)
(Miconazole Nitrate 100 mg per application)

VAGINAL ANTIFUNGAL

CURES MOST VAGINAL YEAST INFECTIONS

and relieves associated external itching and irritation

CLINICALLY PROVEN

MULTI-SYMPTOM RELIEF

COMBINATION PACK

TRIPLE ACTION

#1 DOCTOR

RECOMMENDED BRAND†

Net Wt. 1.59 oz. (45g) • 0.32 oz. (9g) tube

**COMPLETE
THERAPY
SYSTEM™**

**CURES THE INFECTION
RELIEVES THE SYMPTOMS**

COOL

1

6 COOLWIPES®

CURE

2

original prescription strength
cream with 7 applicators

ITCH RELIEF

3

soothing
itch relief cream

7 DAY TREATMENT • CREAM

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If you have questions or comments, call-toll free 877-MONISTAT
or visit our website at www.monistat.com

Distributed by: INSIGHT Pharmaceuticals, LLC.





Trevoze, PA 19053
 © 2012
 40-72-222A 282190
 Made In Canada

3 63736 44960 5

5.844

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

SCAN FOR MORE
 INFORMATION

† Based on a 2012 survey among OB/GYNs and primary care physicians who recommend an over-the-counter brand of vaginal yeast treatments.

VISIT OUR WEBSITE AT WWW.MONISTAT.COM

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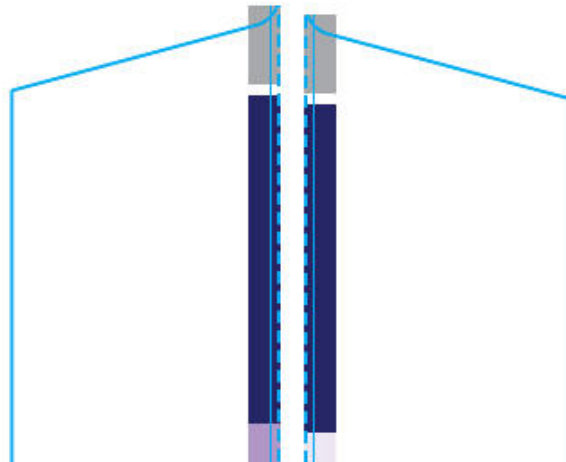
Purpose
 Vaginal antifungal

Drug Facts

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

MONISTAT⁷

COMBINATION PACK



OPEN HERE

STATAT[®] MONI[®]

Miconazole Nitrate Vaginal Cream (2%) and Miconazole Nitrate Cream (2%)
(Miconazole Nitrate 100 mg per application)

VAGINAL ANTIFUNGAL

COOLWIPES[®] FEMININE WIPES

Ingredients: Water, Propylene Glycol, Aloe Barbadosis Leaf Juice, Tocopheryl Acetate, PEG-75Laroln, Disodium Cocoamphodiacetate, Polysorbate 20, Fragrance, Citric Acid, Disodium Phosphate Disodium EDTA, 2-Bromo-2-Nitropropane-1,3-diol, Iodopropynyl Butylcarbamate.

Do not use to remove vaginal treatment or e applied.

EXPIRATION DATE
LOT #

NON-VARNISH AREA



282190

no varnish

no varnish



061282



MONISTAT 7 COMBINATION PACK TRIPLE ACTION

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-003
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-003-07	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE, WITH APPLICATOR	0.1 g
Part 2	1 TUBE	0.009 g

Part 1 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		0.1 g in 1 TUBE, WITH APPLICATOR		

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

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PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.009 g in 1 TUBE		

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	04/26/1993	

Labeler - Insight Pharmaceuticals (176792315)

Establishment

Name	Address	ID/FEI	Business Operations
Jubilant		246762764	MANUFACTURE(63736-003)

Revised: 3/2013

Insight Pharmaceuticals