

MONISTAT 3 COMBINATION PACK- miconazole nitrate
Apex International Mfg., Inc.

MONISTAT 3 Combination Pack - prefilled app and cream

DRUG FACTS

Active ingredients

Purpose

Miconazole nitrate 4% (200 mg in each applicator) 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 suppository 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** suppository 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)

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[®]

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

Miconazole Nitrate Vaginal Cream (4%) and Miconazole Nitrate Vaginal Cream (2%)
(Miconazole Nitrate 200 mg per applicator plus 2% external vulvar cream)

VAGINAL ANTIFUNGAL

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

3 PREFILLED APPLICATORS

plus External Cream for Itch Relief

Net Wt. 0.18 oz (5g) each applicator
+ 0.32 oz (9g) Tube

**3-DAY
TREATMENT**

COMBINATION PACK

Prefilled Cream

3 Ready-to-Use Prefilled Applicators plus External Cream for Itch Relief

**TAMPER-EVIDENT UNIT DO NOT
USE IF **PRINTED** APPLICATOR
WRAPPER IS TORN, OPEN OR
INCOMPLETELY SEALED.**

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

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3-DAY
TREATMENT
COMBINATION PACK

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VAGINAL ANTIFUNGAL

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Exp
Lot



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Drug Facts (continued)

Stop use and ask a doctor if:

- symptoms do not get better in 3 days
- symptoms last more than 7 days
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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 applicator into the vagina at bedtime for 3 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.

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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
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Inactive ingredients benzic acid, cetyl alcohol, isopropyl myristate, polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearic alcohol

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Drug Facts

Active ingredient
Miconazole nitrate 4% (200 mg in each applicator).....Vaginal antifungal
Miconazole nitrate 2% (external cream).....Vaginal antifungal

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- treats vaginal yeast infections
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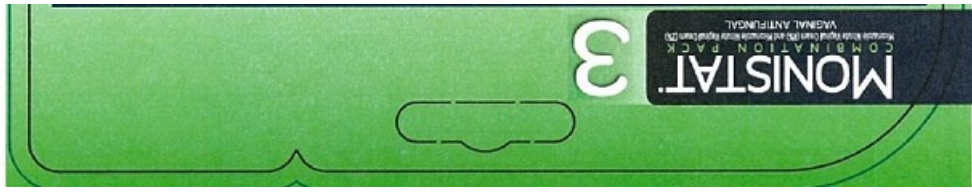
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- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur
- if you do not get complete relief ask a doctor
- before using another product



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MONISTAT 3 COMBINATION PACK

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57501-006
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57501-006-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	06/11/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 APPLICATOR	3 g
Part 2	1 TUBE	9 g

Part 1 of 2**MONISTAT 3**

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	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: 059QF0K00R)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

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	NDA020670	06/11/2020	

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	10 mg in 0.5 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	06/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	06/11/2020	

Labeler - Apex International Mfg., Inc. (015226132)

Registrant - Apex International Mfg., Inc. (079110793)

Establishment

Name	Address	ID/FEI	Business Operations
Apex International Mfg., Inc.		079110793	manufacture(57501-006)

Revised: 4/2020

Apex International Mfg., Inc.