

MONISTAT 3 COMBINATION PACK - miconazole nitrate
Physicians Total Care, Inc.

MONISTAT®3
COMBINATION PACK

Miconazole Nitrate Vaginal Suppositories (200 mg) and Miconazole Nitrate Vaginal Cream (2%)
Vaginal Antifungal

DRUG FACTS

<i>Active ingredients</i>	<i>Purpose</i>
Miconazole nitrate (200 mg in each suppository)	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:
- **suppositories**: 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 blister is torn, open or incompletely sealed
- do not use if seal over tube opening has been punctured or embossed design  is not visible
- do not purchase if carton is open
- store at 20°-25°C (68°-77°F)

Inactive ingredients

suppository: hydrogenated vegetable oil base

external cream: 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

Visit our website @ www.monistat.com

PRINCIPAL DISPLAY PANEL

54868-4238-0

**MONISTAT® 3
COMBINATION PACK**

**Miconazole Nitrate Vaginal Suppositories (200mg) and Miconazole Nitrate Vaginal Cream (2%)
Vaginal Antifungal**

(Miconazole Nitrate 200 mg per suppository plus 2% external vulvar cream)

CURES MOST VAGINAL YEAST INFECTIONS

AND RELIEVES ASSOCIATED EXTERNAL ITCHING AND IRRITATION

ORTHO

**3 Vaginal Suppositories with Disposable
Applicators plus External Cream**

Net Wt. 3 Suppositories

0.32 oz (9g) tube



Additional barcode labeling by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

MONISTAT 3 COMBINATION PACK

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-4238 (NDC:30014-016)
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-4238-0	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

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

Part 1 of 2

MONISTAT 3

miconazole nitrate suppository

Product Information

Route of Administration	VAGINAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	200 mg
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Inactive Ingredients

Ingredient Name	Strength
corn oil (UNII: 8470G57WFM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	03/27/2012	

Part 2 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	10 mg in 0.5 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MM)	
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		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA020670	03/27/2012	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA020670	03/27/2012	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment			
Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 4/2012

Physicians Total Care, Inc.