

MONISTAT 1 COMBINATION PACK- miconazole nitrate
Insight Pharmaceuticals

Monistat® 1 Combination Pack

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Miconazole nitrate 1200 mg (in vaginal insert)	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:
 - **vaginal insert:** with the applicator, place the vaginal insert into the vagina. 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 (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 **printed** sealed pouch 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)
- this is a 1-dose treatment. Most women do not get complete relief of their symptoms in just 1 day. Most women get some improvement in 1 day and complete relief by 7 days.

Inactive ingredients

- vaginal insert: gelatin, glycerin, lecithin, mineral oil, titanium dioxide, white petrolatum
- external cream: 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.
Trevose, PA 19053

PRINCIPAL DISPLAY PANEL - Kit Carton

1 DAY TREATMENT • OVULE[®] INSERT

MONISTAT[®] 1

Miconazole Nitrate Vaginal Insert (1200mg) and Miconazole Nitrate Cream (2%)

VAGINAL ANTIFUNGAL

CLINICALLY PROVEN

MULTI-SYMPTOM RELIEF

CURES MOST VAGINAL YEAST INFECTIONS

and relieves associated external itching and irritation

COMBINATION PACK

1 DOCTOR

RECOMMENDED BRAND[†]

Net Wt. 1 OVULE[®] Insert • 0.32oz (9g) tube



SCAN FOR MORE INFORMATION

VISIT OUR WEBSITE AT WWW.MONISTAT.COM

Drug Facts (continued)

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Questions? call toll-free 877-666-4792

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1 DAY COMBINATION PACK

CURES MOST VAGINAL YEAST INFECTIONS

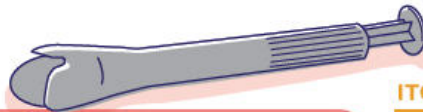
Miconazole Nitrate Vaginal Insert (1200mg) and Miconazole Nitrate Cream (2%)
VAGINAL ANTIFUNGAL

MONISTAT[®] 1

DUAL ACTION SYSTEM

CURES THE INFECTION RELIEVES THE SYMPTOMS FAST

1 CURE ExpressRelease OVULE[®] Insert



2 ITCH RELIEF soothing itch relief cream



MONISTAT[®] 1

Miconazole Nitrate Vaginal Insert (1200mg) and Miconazole Nitrate Cream (2%)
VAGINAL ANTIFUNGAL

CURES MOST VAGINAL YEAST INFECTIONS and relieves associated external itching and irritation

COMBINATION PACK

1 DAY TREATMENT • OVULE[®] INSERT

MONISTAT[®] 1

Miconazole Nitrate Vaginal Insert (1200mg) and Miconazole Nitrate Cream (2%)
VAGINAL ANTIFUNGAL

CURES MOST VAGINAL YEAST INFECTIONS and relieves associated external itching and irritation



COMBINATION PACK

#1 DOCTOR
RECOMMENDED BRAND[†]

Net Wt. 1 OVULE[®] Insert • 0.32oz (9g) tube

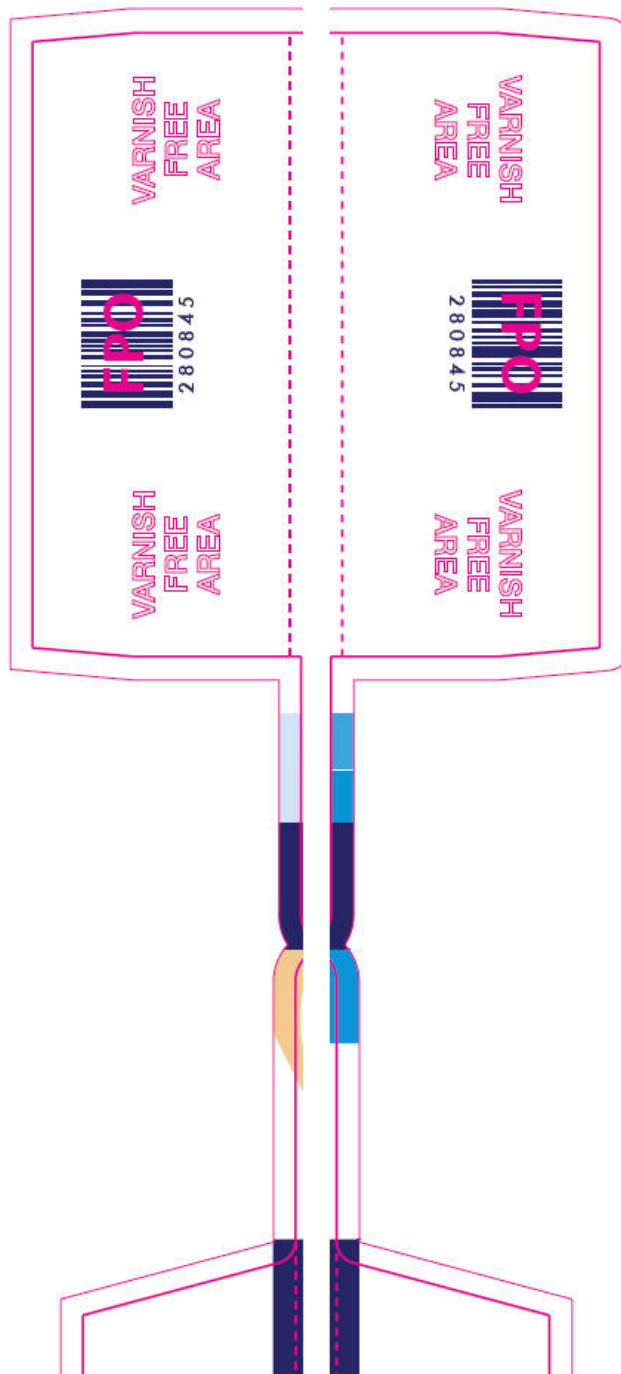


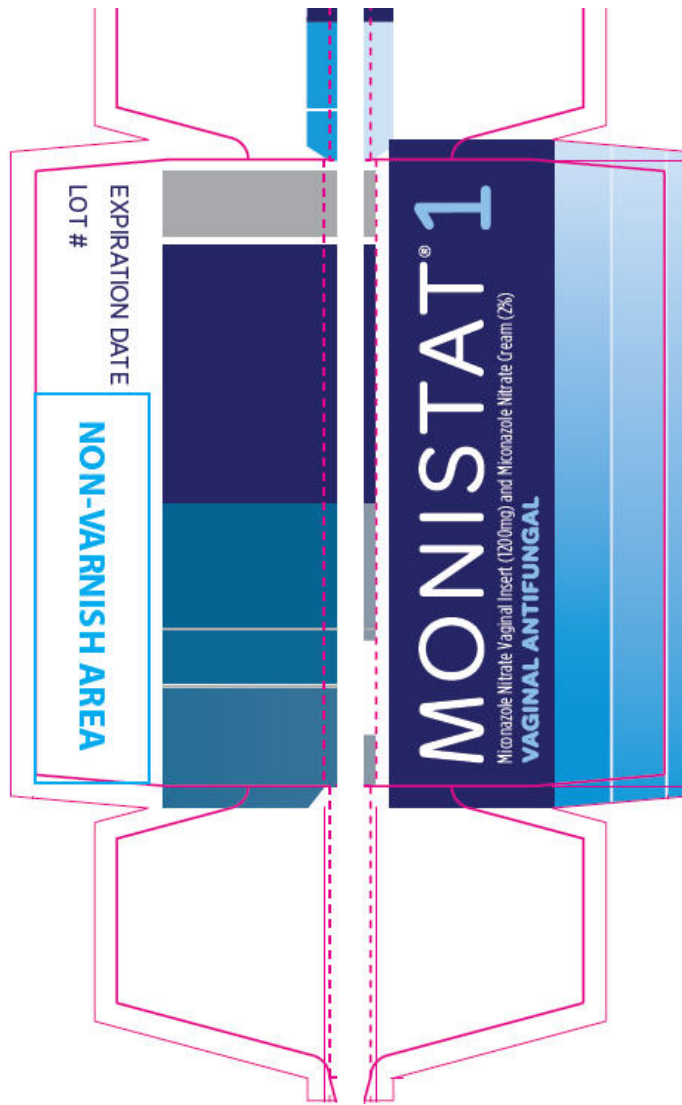
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Trevose, PA 19053
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40-72-140C 280845
US Patent Number 7,198,612
Made in Belgium

TAMPER-EVIDENT UNIT
DO NOT USE IF PRINTED
SEALBD POUCH IS
TORN, OPEN OR
INCOMPLETELY SEALED

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

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





MONISTAT 1 COMBINATION PACK

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-014
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-014-03	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 POUCH	1
Part 2	1 TUBE	9 g

Part 1 of 2

MICONAZOLE NITRATE

miconazole nitrate suppository

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	1200 mg

Inactive Ingredients

Ingredient Name	Strength
Gelatin (UNII: 2G86QN327L)	
Glycerin (UNII: PDC6A3C0OX)	
Mineral Oil (UNII: T5L8T28FGP)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021308	06/29/2001	

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
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Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	20 mg in 1 g
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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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021308	06/29/2001	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021308	06/29/2001	

Labeler - Insight Pharmaceuticals (176792315)

Establishment

Name	Address	ID/FEI	Business Operations
Jubilant		246762764	MANUFACTURE(63736-014)

Revised: 3/2013

Insight Pharmaceuticals