
Monistat[®] 1 Combination Pack

Drug Facts

Active ingredients	Purpose		
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

$1 \text{ DAY TREATMENT} \bullet OVULE^{\circledast} \text{ INSERT}$

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

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1 DAY COMBINATION PACK

CURES MOST VAGINAL YEAST INFECTIONS

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

GURES THE INFECTION RELIEVES THE SYMPTOMS FAST



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

CURES MOST VAGINAL YEAST INFECTIONS

and relieves associated external itching and irritation

MONISTA

COMBINATION PACK

DUAL

SYSTEM

1 DAY TREATMENT • OVULE® INSERT



VAGINAL ANTIFUNGAL

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



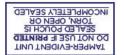
COMBINATION PACK

Net Wt.1 OVULE" Insert • 0.32oz (9g) tube

#1 DOCTOR RECOMMENDED BRAND[†]

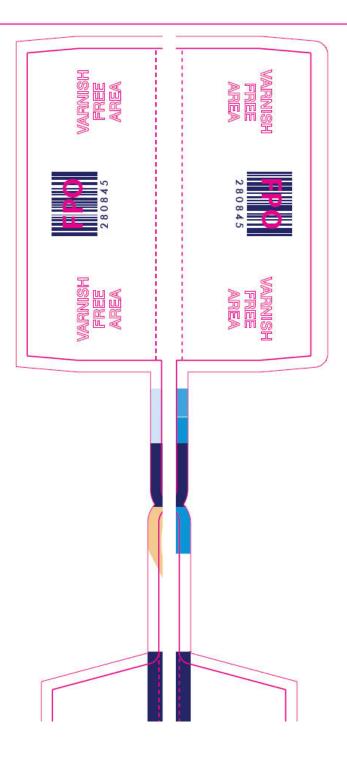
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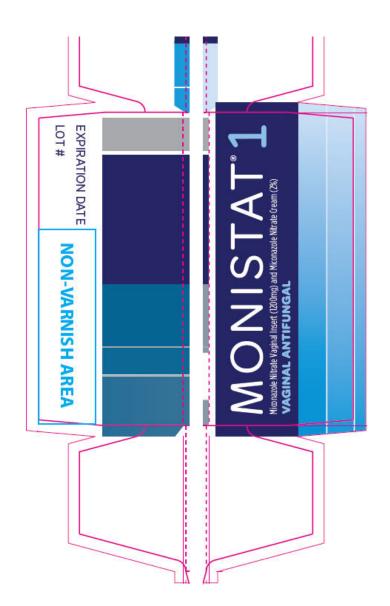
Distributed by: INSIGHT Pharmaceuticals, LLC. Trevose, PA 19053 @ 2012 0.72-140C 280845 US Patent Number 7,198,612 US Patent Number 7,198,612 Made in Belgum



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

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





niconazole nitrate kit						
Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-014			
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

ΜΙΟΟΝΑΖΟΙ Ε ΝΙΤΡΑΤΕ

miconazole nitrate suppository								
miconazole nitrate suppository								
Produ	uct Informati	ion						
Route	of Administrati	ion	VAGINAL					
Active	e Ingredient/	Active Moi	o fx/					
	e ingreatent/		gredient Name			Basis	of Strength	Strength
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	in (UNII: PDC6A3							
	I Oil (UNII: T5L8							
Titaniu	ım Dioxide (UNI	I: 15FIX9V2JP)						
Petrola	tum (UNII: 4T6H	I12BN9U)						
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Inactive Ingredients					
Ingredient Name					Strength
Benzoic Acid (UNII: 8	SKN0B0MIM)				
Cetyl Alcohol (UNII: 936JST6JCN)					
Isopropyl Myristate (Isopropyl Myristate (UNII: 0 RE8 K4LNJS)				
Polysorbate 60 (UNII:	CAL22UVI4M)				
Potassium Hydroxide	(UNII: WZH3C48M4T)				
Propylene Glycol (UN	II: 6DC9Q167V3)				
Water (UNII: 059QF0F	O0R)				
Stearyl Alcohol (UNII	2KR89I4H1Y)				
Packaging					
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Labeler - Insight Pharmaceuticals (176792315)

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

Revised: 3/2013

Insight Pharmaceuticals