MICONAZOLE 3 COMBINATION PACK- miconazole nitrate Major Pharmaceuticals

Miconazole 3 Combination Pack

Drug Facts

Active ingredients

Miconazole nitrate, USP 200 mg (in each suppository) Miconazole nitrate, USP 2% (external cream)

Purpose

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 and 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.

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 foulsmelling 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 applicator away after use.
 - **external cream:** Use cap to puncture seal. 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 suppository wrapper is missing or damaged (each suppository is individually wrapped)
- do not use if seal over tube opening has been punctured or is not visible
- do not purchase if carton is open
- store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F).

Inactive ingredients

- suppository: hydrogenated vegetable oil
- external cream: benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxylglycerides, pegoxol 7 stearate, purified water

Questions?

1-888-838-2872 between 9 am and 5 pm ET, Monday-Friday.

Principal display panel

Compare to the active ingredient in Monistat® 3* Miconazola 3 Combination Pack Miconazole Nitrate Vaginal Suppositories, USP 200 mg and Miconazole Nitrate Vaginal Cream, USP 2% 200 mg/2% Vaginal Antifungal Cures most vaginal yeast infections Relieves associated external itching and irritation 3 Miconazole Nitrate Vaginal Suppositories, USP 200 mg with 3 disposable applicators plus 1 tube of Miconazole Nitrate Vaginal Cream, USP 2% NET WT. 0.32 OZ (9g) TUBE *This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat® 3. Retain carton for complete information. Distributed by: MAJOR[®] PHARMACEUTICALS

17177 N Laurel Park Drive

Suite 233

Livonia, MI 48152, USA

Package label



Other information m do not use if suppositing wrapper is missing or damaged (each suppository is individually wrapped) m do not use if seal over tube opening has been punctured or is not visible m do not purchase if carton is open
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sibe Facto

MAJOR Vaginal Antifungal Cream

MICONAZOLE 3 COMBINATION PACK miconazole nitrate kit								
Р	Product Information							
	Product Type HUMAN OTC DRUG Item Code (Source) NDC:0904-5415							
P	roauc	туре		HUMAN OTC DRUG	item Code (So	urce)	NDC:0904-5415	
P	acka	ging						
#	lten	n Code		Package Description	on	Marketing Star Date	rt Marketing End Date	
1	NDC:0 5415-			ACKAGE, COMBINATION; Type ation Product	0: Not a	12/02/2002		
Quantity of Parts								
Pa	art #		Pac	kage Quantity		Total Product Q	uantity	
Pa	art 1	1 BLISTE	R PACK		3 in 0			
Pa	art 2	1 TUBE			9 g			
Part 1 of 2								
MICONAZOLE 3 miconazole nitrate suppository								
				PP-0-10-1				

Product Info	rmation					
Route of Admin		VAGINAI				
Route of Admin	ilstration	VAGINAL				
Active Ingred	lient/Active	Moiety				
	Ingi	redient Name		Basis of	Strength	Strength
MICONAZOLE NI	TRATE (UNII: VW	H1CYW1K) (MICONAZOLE - UNII:7	NNO0D7S5M	I) MICONAZOI	LE NITRATE	200 mg
Inactive Ingr	edients					
indetite ingi	culonio	Ingredient Name			St	rength
HYDROGENATED	PALM KERNEL	OIL (UNII: FM8D1RE2VP)				
Packaging						
# Item Code	Pack	age Description		ing Start ate		ting End ate
	in 1 BLISTER PAC oduct	K; Type 0: Not a Combination				
Marketing	Informat	ion				
Marketing Category	Applicat	tion Number or Monograph Citation	Mark	eting Start Date		eting End Date
ANDA	ANDA07492	6	12/02/20	002		
Part 2 of 2						
MICONAZO	OLE 3					
miconazole niti	rate cream					
Product Info	rmation					
Route of Admin	nistration	VAGINAL				
Active Ingred	lient/Active	Moiety				
		edient Name		Basis o		Strength
MICONAZOLE	-			Streng	tn	-
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M) MICONAZOLE NITRATE 10 mg in 0.5 g						
Inactive Incr	odionts					
Inactive Ingr	edients	Ingradiant Name			C	rongth
		Ingredient Name			51	trength

BENZOIC ACID	BENZOIC ACID (UNII: 85KN0B0MIM)								
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)									
MINERAL OIL (MINERAL OIL (UNII: T5L8T28FGP)								
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)									
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)									
WATER (UNII: 059QF0KO0R)									
Packaging									
# Item Code	Packag	e Description	М	Marketing Start M Date		Marketing End Date			
1	9 g in 1 TUBE; Type Product	0: Not a Combination							
Markotin	a Informati	n							
Marketing Information									
Marketin Category		on Number or Monograph Citation		Marketing Start Date		Marketing End Date			
ANDA	ANDA074926			12/02/2002					
Marketing Information									
Marketin Category		on Number or Monogra Citation	ph	Marketing Start Date		Marketing End Date			
ANDA	ANDA074926			12/02/2002					

Labeler - Major Pharmaceuticals (191427277)

Revised: 12/2022

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