

MICONAZOLE 7- miconazole nitrate cream
Preferred Pharmaceuticals Inc.

Miconazole 7

Drug Facts

Active ingredient

Miconazole nitrate USP, 2% (100 mg in each applicator)

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 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 (1-800-222-1222) 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:**
 - o **applicator:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Wash applicator after use.
 - o use the same tube of cream if you have itching and irritation on the skin outside the vagina. Squeeze a small amount of cream onto your fingertip. Apply to 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

- to open tube: unscrew cap, lift tab, and pull to remove foil seal prior to use
- do not use if foil seal on tube opening is broken or missing
- do not purchase if carton is open
- store at room temperature 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F)
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxyglycerides, pegoxol 7 stearate, purified water

Questions?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Distributed by: **H2-Pharma, LLC**
Montgomery, AL 36117

Relabeled By: Preferred Pharmaceuticals Inc.

PRINCIPAL DISPLAY PANEL - 45 g Tube Carton

NDC 68788-7917-4

*Compare to the active ingredient in Monistat® 7 Vaginal Cream

Miconazole 7

Miconazole Nitrate Vaginal Cream, USP 2% (Miconazole Nitrate 100 mg per applicator)

Vaginal Antifungal

Cures most vaginal yeast infections
Relieves associated external itching and irritation

Net wt. 1.59 oz (45 g) Tube
7 day vaginal cream (1 tube) with 1 reusable applicator

H²pharma

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<p>Miconazole Nitrate Vaginal Cream 2% Generic for Monistat 7 Cream Active ingredient (in each applicator): Miconazole Nitrate USP 2% (100mg per applicator)...Vaginal Antifungal Pkg Size: Exp Date: Lot#: Batch#: Ins: Mfg: H2-Pharma, LLC Prod#: Warning <small>Relieves external vulvar itching and irritation associated with a yeast infection. For vaginal use only. Do not use if you have never had a vaginal yeast infection diagnosed by a doctor. See box for additional warnings, drug facts, and directions. Do not use if seal over tube opening has been punctured or cannot be seen. Store at 20°-25° (68°-77° F); excursions permitted to 15°-30°C (59°-86° F). See USP Controlled Room Temperature.</small></p>	 <p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p>	<p>Miconazole Nitrate Vaginal Cream 2% Qty: Ins: Lot#: Bat#:</p>	Log
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Directions English Use as directed on package.</p>		<p>Prod# (NDC): Miconazole Nitrate Vaginal Cream 2% Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	Chart
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Instrucciones Español: Utilice como dirigido en el paquete.</p>		<p>Miconazole Nitrate Vaginal Cream 2% Qty: Ins: Insurance NDC: Lot#: Bat#:</p>	Billing
		<p>Miconazole Nitrate Vaginal Cream 2% Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	Patient

MICONAZOLE 7			
miconazole nitrate cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7917(NDC:61269-730)
Route of Administration	VAGINAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	MICONAZOLE NITRATE (UNII: V44U11C0M5) (MICONAZOLE		

MICONAZOLE NITRATE (UNII: VV4H1CTW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE 20 mg in 1 g
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Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MINERAL OIL (UNII: T5L8T28FGP)	
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	
WATER (UNII: 059QF0KOOR)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7917-4	1 in 1 CARTON	05/27/2021	
1		45 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074164	05/27/2021	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-7917)