# 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 foulsmelling 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:
  - **applicator:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Wash applicator after use.
  - 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 polyoxylglycerides, 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

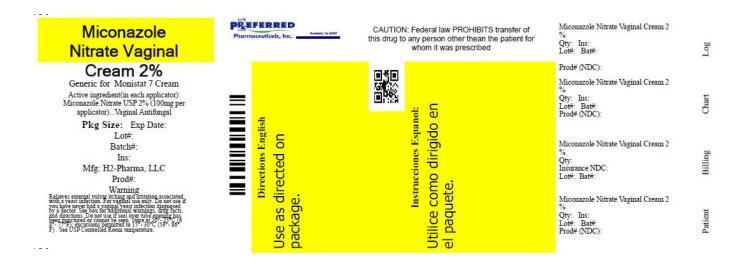
Miconazole Nitrate Vaginal Cream, USP 2% (Miconazole Nitrate 100 mg per applicator)

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  $H^2$ pharma

# Relabeled By: Preferred Pharmaceuticals Inc.



# 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

Ingredient Name	Strength

BENZOIC ACID (UNII: 85KN0B0MIM)

**BUTYLATED HYDROXYANISOLE** (UNII: REK4960K2U)

MINERAL OIL (UNII: T5L8T28FGP)

APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)

PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)

WATER (UNII: 059QF0KO0R)

_		_				
Р	rod	uct	Cha	ract	erist	tics

1 1 0 4 4 4 5 1 5 1 6 5 1				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

_					-	
D	2	•	$\nu$ 2	~	In	$\sim$
	a	·	ka	ч	ши	ч

П	. ackaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	<b>1</b> 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	<b>Business Operations</b>	
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-7917)	

Revised: 8/2023 Preferred Pharmaceuticals Inc.