#### 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 foulsmelling 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:
  - o **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

## **PRINCIPAL DISPLAY PANEL - 45 g Tube Carton**

NDC 68788-7917-4

\*Compare to the active ingredient in Monistat  $^{\ensuremath{\mathbb{R}}}$  7 Vaginal Cream

Miconazole 7

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

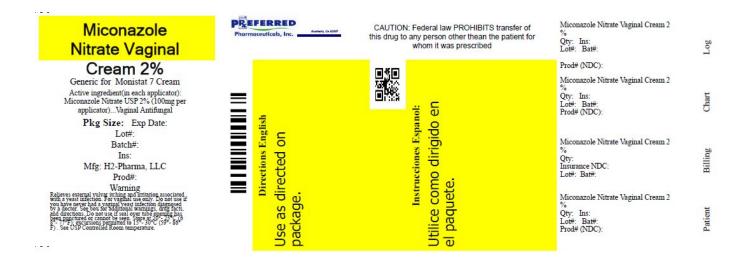
Vaginal Antifungal

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<sup>2</sup>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								
Ingi	<b>Basis of Strength</b>	Strength						

	active Ingr					Strength				
Ingredient Name										
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)										
W	ATER (UNII: 059	QF0KO0R)								
п.	aduat Cha	racteristics								
		racteristics		-						
Color		WHITE	Score							
Shape			Size							
Flavor			Imprint Code							
Contains										
Packaging										
10										
<b>#</b>	Item Code	Pa	ckage Descripti	on	Marketing Start Date	Marketing End Date				
#		Pa 1 in 1 CARTON	ckage Descripti	on	-					
# 1	Item Code NDC:68788-	1 in 1 CARTON	MTH APPLICATOR; Typ		Date					
#	Item Code NDC:68788-	1 in 1 CARTON 45 g in 1 TUBE, V	MTH APPLICATOR; Typ		Date					
# 1 1	Item Code NDC:68788- 7917-4	1 in 1 CARTON 45 g in 1 TUBE, V	MTH APPLICATOR; Typ Juct		Date					

ANDA074164

**Registrant -** Preferred Pharmaceuticals Inc. (791119022)

# **Establishment**

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

05/27/2021

Revised: 7/2024

ANDA

Preferred Pharmaceuticals Inc.