

**MICONAZOLE 7- miconazole nitrate cream**  
**Preferred Pharmaceuticals Inc.**

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**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

H<sup>2</sup>pharma

**Relabeled By: Preferred Pharmaceuticals Inc.**



**MICONAZOLE 7**

miconazole nitrate cream

**Product Information**

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68788-7917(NDC:61269-730) |
| <b>Route of Administration</b> | VAGINAL        |                           |                               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength  | Strength     |
|---|--------------------|--------------|
| <b>MICONAZOLE NITRATE</b> (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) | MICONAZOLE NITRATE | 20 mg in 1 g |

## Inactive Ingredients

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

## Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | WHITE | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

## 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) |

Revised: 8/2025

Preferred Pharmaceuticals Inc.