

MICONAZOLE 7- miconazole nitrate suppository
H2-Pharma, LLC

Miconazole 7

Drug Facts

Active ingredient (in each vaginal suppository)

Miconazole nitrate, USP 100 mg

Purpose

Vaginal antifungal

Use

- treats vaginal yeast infections

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**
- **vaginal yeast infections often (such as once a month or 3 in 6 months). You may have a more serious condition. You could be pregnant or have a medical condition, such as diabetes or a weakened immune system.**
- lower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge
- 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
- do not use condoms or diaphragms. They may be damaged by this product and not prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse (sex)
- mild increase in vaginal burning, itching or irritation may occur

Stop use and ask a doctor if

- **side effects occur**
- **symptoms do not get better after 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 instructions and information
- adults and children 12 years of age and over: insert 1 suppository into the vagina at bedtime for 7 nights in a row. Wash applicator after use.
- children under 12 years: ask a doctor

Other information

- do not purchase if carton is open
- each suppository is individually wrapped. Do not use if wrapper is missing or damaged.
- store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F)

Inactive ingredient

hydrogenated vegetable oil

Questions?

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

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

PRINCIPAL DISPLAY PANEL - 100 mg Suppository Box

NDC 61269-736-07

*Compare to the active ingredient in
Monistat® 7

Miconazole 7

Miconazole nitrate
Vaginal suppositories, USP 100 mg
Vaginal antifungal

Cures most vaginal yeast infections

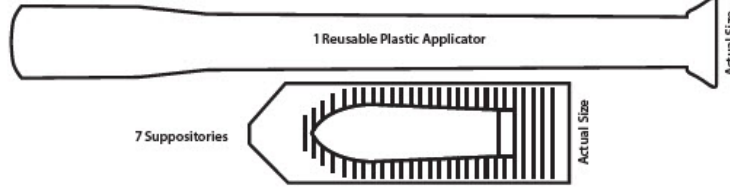
7 vaginal suppositories with 1 reusable plastic applicator

H² pharma

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Lot/Exp Print Area

Distributed by: H2-Pharma, LLC
Montgomery, AL 36117
www.h2-pharma.com

VC710306 PLD-A653A F0006827



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Drug Facts

Active Ingredient (in each vaginal suppository) Miconazole nitrate, USP 100 mg. Vaginal antifungal

Use Treats vaginal yeast infections

Warnings For vaginal use only. Do not use if you have never had a vaginal yeast infection diagnosis by a doctor.

Directions Ask a doctor before use. If you have vaginal yeast infections, ask a doctor before use. If you have had a vaginal yeast infection, ask a doctor before use. If you have had a vaginal yeast infection, ask a doctor before use. If you have had a vaginal yeast infection, ask a doctor before use.

Other Information Each suppository is individually wrapped. Do not use if wrapper is torn, damaged, or missing. Do not use if wrapper is torn, damaged, or missing. Do not use if wrapper is torn, damaged, or missing.

Questions? Call 1-877-736-2335 Monday-Friday 9AM-5PM EST. This product is not affiliated with, manufactured by, or produced by the makers of Monistat® 7.



MICONAZOLE 7

miconazole nitrate suppository

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61269-736 |
| Route of Administration | VAGINAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|----------|
| Miconazole Nitrate (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) | Miconazole Nitrate | 100 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP) | |
| PALM KERNEL OIL (UNII: B0S90M0233) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | WHITE | Score | |
| Shape | OVAL | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:61269-736-07 | 7 in 1 BOX; Type 0: Not a Combination Product | 05/24/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA073507 | 05/24/2021 | |

Labeler - H2-Pharma, LLC (028473634)

