

MICONAZOLE 7- miconazole nitrate cream
H2-Pharma, LLC

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:**
 - **applicator:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Throw applicator away 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 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

PRINCIPAL DISPLAY PANEL - 45 g Tube Carton

NDC 61269-730-41

*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 7 disposable applicators

H²pharma

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22 mm

22 mm

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VARNISH
ON

EMBOSSING
AREA

Miconazole 7

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

30 mm

30 mm

Miconazole 7
Miconazole Nitrate
Vaginal Cream, USP 2%
(Miconazole nitrate 100 mg per applicator)
Vaginal antifungal



This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat®.

Directions ■ Before using this product read the enclosed consumer information leaflet for complete directions and information.
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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
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Uses
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■ Relieves external itching and irritation due to a vaginal yeast infection.

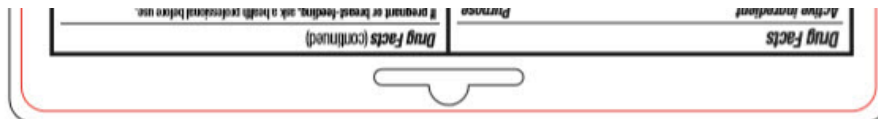
Monistat® 7 Vaginal Cream
Miconazole nitrate (USP) 2% (100 mg) in each applicator.

Distributed by: H2-Pharma, LLC
Montgomery, AL 36117
www.h2-pharma.com
Code: 60/0805/361 PIM36/30

NO
VARNISH

Pharmacia





MICONAZOLE 7

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61269-730
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

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

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:61269-730-41	1 in 1 CARTON	04/12/2021	
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
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ANDA	ANDA074164	04/12/2021	
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Labeler - H2-Pharma, LLC (028473634)

Revised: 1/2023

H2-Pharma, LLC