

MICONAZOLE 7- miconazole nitrate cream

Major Pharmaceuticals

Miconazole Nitrate Vaginal Cream, USP

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. 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)
- before using any medication, read all label direction. 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

Principal display panel

Compare to the active ingredient in Monistat® 7 Vaginal Cream*

Miconazole 7

Miconazole Nitrate USP 2%

Vaginal cream (Miconazole Nitrate 100 mg per applicator)

Vaginal Antifungal

Cures most vaginal yeast infections

Relieves associated external itching and irritation

7 day vaginal cream (1 tube) with 1 reusable applicator

NET WT OZ (g) Tube

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

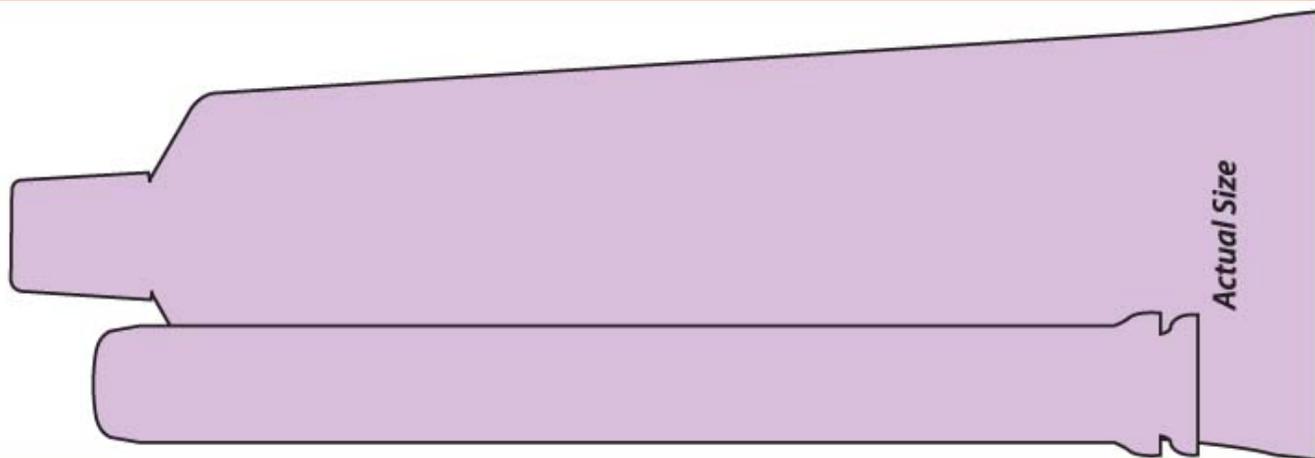
Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

Package label

<p>Drug Facts</p> <p>Active ingredient Miconazole nitrate USP, 2% (100 mg in each applicator).....Vaginal antifungal</p> <p>Purpose Vaginal antifungal</p> <p>Uses ■ treats vaginal yeast infections ■ relieves external itching and irritation due to a vaginal yeast infection</p> <p>Warnings For vaginal use only</p> <p>Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.</p> <p>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</p> <p>Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur.</p> <p>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</p> <p>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</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p>Directions ■ before using this product read the enclosed consumer information leaflet for complete directions and information</p> <p>■ 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 (vulva). 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.</p> <p>■ children under 12 years of age: ask a doctor</p> <p>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°-25°C (68°-77°F) ■ before using any medication, read all label directions. Keep carton; it contains important information.</p> <p>Inactive ingredients benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxyglycerides, pectin, purified water</p> <p>Questions? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p> <p><small>*This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat®.</small></p>
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MAJOR®

NDC 0904-7734-45

compare to the active ingredient in
Monistat® 7 Vaginal Cream*

miconazole 7

miconazole nitrate USP, 2%
vaginal cream (miconazole nitrate 100 mg per applicator)
vaginal antifungal

- cures most vaginal yeast infections
- relieves associated external itching and irritation

7 day vaginal cream (1 tube) with 1 reusable applicator

net wt. 1.59 oz (45 g) tube

MAJOR* PHARMACEUTICALS
Indianapolis, IN 46268
(800) 618-2471
www.major-rugby.com

Product of India Rev. 09/24 M-58 Re-order No. 700604

PLD-F655C FC009118



Code: GO/DRUGS/361 AAP3A/06

MAJOR Vaginal Antifungal Cream

MICONAZOLE 7

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7734
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: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0904-7734-57	1 in 1 CARTON	06/01/2009	08/31/2017
1		45 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		
2	NDC:0904-7734-45	1 in 1 CARTON	04/21/2009	
2		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	04/21/2009	

Labeler - Major Pharmaceuticals (191427277)

Revised: 10/2024

Major Pharmaceuticals