MICONAZOLE 7- miconazole nitrate cream EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC)

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 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:
 - **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°-25°C (68°-77°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?

1-888-287-1915

Principal display panel

Compare to Monistat® 7 active ingredient*

7 Day Treatment

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

7 Day Vaginal Cream (1 Tube) with

7 Disposable Applicators

Net wt. 1.59 oz (45g) Tube

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

DISTRIBUTED BY: Wal-mart Inc.,

Bentonville, AR 72716

Package Label



MICONAZOLE 7

miconazole nitrate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49035-347

Route of Administration VAGINAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNOOD7S5M)	MICONAZOLE NITRATE	100 mg in 1 a

Inactive Ingredients

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Ingredient Name	Strength				
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)					
WATER (UNII: 0590F0KO0R)					

Product Characteristics

Combination Product

1

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging Marketing Start Marketing End # Item Code **Package Description** Date Date **1** NDC:49035-347-07 7 in 1 CARTON 05/01/2020 45 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA074164	05/01/2020				

Labeler - EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC) (051957769)

Revised: 9/2024

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