MICONAZOLE 7- miconazole nitrate cream CVS Pharmacy

Miconazole 7

Drug Facts

Active ingredient

Miconazole nitrate USP 2%

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 aretaking 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:
 - **applicators:**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 the cream onto the itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days as needed.
- children under 12 years of age: ask a doctor

Other information

- do not use if seal over tube opening has been punctured
- do not purchase if carton is open
- store at 20° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

benzoic acid (0.20%) as a preservative, butylated hydroxytoluene, mineral oil, oleoyl polyoxylglyceride, PEG-6-32 stearate/glycol stearate, and purified water.

Questions?

call **1-866-923-4914**

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 45 g Tube Carton

CVSHealth ™

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

7-Day Treatment

Miconazole 7

MICONAZOLE NITRATE VAGINAL CREAM USP (2%)

Vaginal antifungal

NET WT 1.5 OZ (45 g) TUBE + 7 DISPOSABLE APPLICATORS



MICONAZOLE 7

miconazole nitrate cream

Product	Inform	ation
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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-988
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Route of Administration VAGINAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) MICONAZOLE NITRATE 20 mg in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
MINERAL OIL (UNII: T5L8T28FGP)		
WATER (UNII: 059QF0KO0R)		
BENZOIC ACID (UNII: 85KN0B0MIM)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:69842- 988-07	1 in 1 CARTON	12/15/2016	
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	ANDA074444	01/13/1997	

Labeler - CVS Pharmacy (062312574)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sun Pharma Canada Inc.		243339023	manufacture(69842-988)	

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