MICONAZOLE NITRATE- miconazole nitrate cream NuCare Pharmaceuticals, Inc.

Miconazole Nitrate

Drug Facts

Active ingredient

Miconazole nitrate USP 2% (100 mg in each applicatorful)

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

- do not purchase if carton is opened
- do not use if seal over tube opening has been punctured or is not visible
- 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?

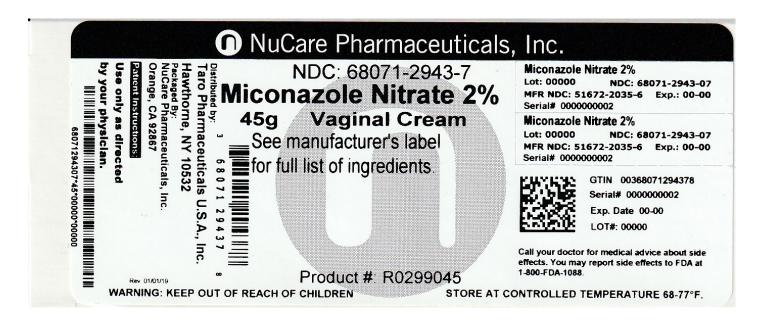
call **1-866-923-4914**

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL



MICONAZOLE NITRATE

miconazole nitrate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68071-2943(NDC:51672-2035)

Route of Administration VAGINAL

Active Ingredient/Active Moiety

Ingredient Name

MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)

Basis of Strength

MICONAZOLE NITRATE 20 mg in 1 g

Inactive Ingredients

Ingredient Name
Strength

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z 171K)

MINERAL OIL (UNII: T5L8T28FGP)

WATER (UNII: 059QF0KO0R)

BENZOIC ACID (UNII: 8SKN0B0MIM)

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
NDC:68071- 2943-7	1 in 1 CARTON	02/23/2023				
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 - NuCare Pharmaceuticals,Inc. (010632300)

Establishment								
Name	Address	ID/FEI	Business Operations					
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-2943)					

Revised: 2/2023 NuCare Pharmaceuticals,Inc.