MICONAZOLE NITRATE- miconazole nitrate cream
Taro Pharmaceuticals U.S.A., 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 - 45 g Tube Carton

CURES most vaginal YEAST INFECTIONS
Relieves associated external itching and irritation

NDC 51672-2035-6

7 Day Treatment

7 Day Vaginal Cream

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

One 45 g (1.5 oz) tube of Miconazole Nitrate Vaginal Cream USP (2%)
& 1 Reusable Applicator

Consumer Information Leaflet Enclosed

MICONAZOLE NITRATE

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2035
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**
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Mineral Oil (UNII: T5L8T28FGP)	
Water (UNII: 059QF0KO0R)	
Benzoic Acid (UNII: 8SKN0B0MIM)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51672-2035-6	1 in 1 CARTON	01/13/1997	
1		45 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		
2	NDC:51672-2035-7	1 in 1 CARTON	01/13/1997	
2		45 g in 1 TUBE, WITH 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 - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2035)

Revised: 1/2020 Taro Pharmaceuticals U.S.A., Inc.