QUALITY CHOICE 3 DAY VAGINAL- miconazole nitrate cream
Chain Drug Marketing Association

Quality Choice®
3 Day Vaginal

Drug Facts

Active ingredient (in each applicator)

Miconazole Nitrate USP 4% (200 mg in each applicator)

Purpose

Vaginal antifungal

Use

treats vaginal yeast infections

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 right away.

Directions

- before using this product read the consumer information leaflet for complete directions and information
- adults and children 12 years of age and over:
  - insert 1 applicatorful into the vagina at bedtime for 3 nights in a row. Throw applicator away after use.
- children under 12 years of age: ask a doctor

Other information

- store at 20°-25°C (68°-77°F)
- do not purchase if carton is open
- see end flaps of carton and end of tube for lot number and expiration date
- the tube opening should be sealed. If seal has been broken, do not use product.

Inactive ingredients

cetyl alcohol, isopropyl myristate, polysorbate 60, polysorbate 80, potassium hydroxide, propylene glycol, purified water, sorbitan monostearate and stearyl alcohol

Questions or comments?

Call toll-free, **1-800-935-2362**, for our 24 hour automated response system.

**DISTRIBUTED BY QUALITY CHOICE 43157 WEST NINE MILE ROAD
NOVI, MI 48376-0995**

PRINCIPAL DISPLAY PANEL - 25 g Tube Carton

**QC
QUALITY
CHOICE®**

Cures Most Vaginal Yeast Infections

3 Day Vaginal Cream

Miconazole Nitrate Vaginal Cream USP (4%)

Vaginal Antifungal

(Miconazole Nitrate 200 mg per applicator)

**One 0.9 oz (25 g) tube of 3 Day Vaginal Cream with 3 Disposable Applicators
Consumer Information Leaflet Enclosed**

NDC 63868-197-25

Compare to the Active Ingredient in Monistat® 3*

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LPK-6573-0
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* This product is not manufactured or distributed by Johnson & Johnson owner of the registered trademark Monistat® 3.

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QC 96614
Made in Canada
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SATISFACTION QC GUARANTEED

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VARNISH FREE

VARNISH FREE

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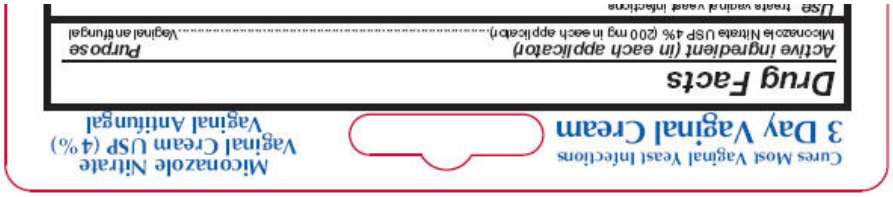

QUALITY CHOICE 3 DAY VAGINAL

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-197
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63868-197-25	1 in 1 CARTON		
1		25 g in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076773	03/02/2005	

Labeler - Chain Drug Marketing Association (011920774)

Registrant - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(63868-197)