

MICONAZOLE 3- miconazole nitrate cream
Shopko Stores Operating Co., LLC

Miconazole 3

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?

Call **1-866-923-4914**

Manufactured for Shopko
By Taro Pharmaceuticals Inc.
Brampton, Ontario, Canada L6T 1C1

PRINCIPAL DISPLAY PANEL - 25 g Tube Carton

SHOPKO®

Miconazole 3

Miconazole Nitrate Vaginal Cream USP (4%)

Vaginal Antifungal

(Miconazole Nitrate 200 mg Per Applicator)

3 Day Treatment

Consumer Information

Leaflet Enclosed

NDC 37012-070-09

*Compare to the active
ingredient in Monistat® 3*

One 0.9 oz (25 g) Tube of 3 Day Vaginal Cream with **3** Disposable Applicators

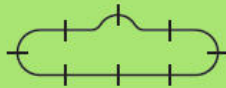
SHOPKO®

3 Day Treatment

Miconazole 3

Miconazole Nitrate Vaginal Cream USP (4%)

Vaginal Antifungal (Miconazole Nitrate 200 mg Per Applicator)



Compare to the active ingredient in Monistat® 3

LPK-7496-1
0314-1
M852

Cures Most Vaginal Yeast Infections

SHOPKO®

Miconazole 3

Miconazole Nitrate Vaginal Cream USP (4%)

Vaginal Antifungal

(Miconazole Nitrate 200 mg Per Applicator)

3 Day Treatment

NDC 37012-070-09

Compare to the active ingredient in Monistat® 3



SHOPKO®

Miconazole 3

Miconazole Nitrate Vaginal Cream USP (4%)
Vaginal Antifungal
(Miconazole Nitrate 200 mg Per Applicator)

3 Day Treatment

NO COPY ON THIS FLAP
FOR LOT # AND EXPIRY
DATE PRINT

Consumer Information
Leaflet Enclosed

One 0.9 oz (25 g) Tube of 3 Day Vaginal Cream with 3 Disposable Applicators

T128B



* This product is not manufactured or distributed by Insight Pharmaceuticals LLC owner of the registered trademark Monistat® 3.

Manufactured for Shopko
By Taro Pharmaceuticals Inc.
Brampton, Ontario, Canada L6T 1C1
1-866-923-4914
©2014 Shopko Stores
Operating Co., LLC
Made in Canada



By Refund Or Exchange

NO VARNISH
ON THIS FLAP



Drug Facts (continued)

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

Use

- treats vaginal yeast infections

Warnings

- 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 in 3 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.

Other information

- 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, spermicide or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted disease (STD).
- 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.

Drug Facts

Active ingredient (in each applicator) Miconazole Nitrate USP 4% (200 mg in each applicator) Vaginal antifungal

Purpose Vaginal antifungal

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.
 - This use applies to all ages.
- children under 12 years of age: ask a doctor

Other information

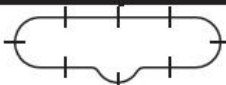
- store at 20°-25°C (68°-77°F)
- do not purchase if carton is open
- see end flaps of carton and end of tube for lot number and expiration date
- the tube opening should be sealed. If seal has been broken, do not use product.

Inactive ingredients cetyl alcohol, isotropyl myristate, polyorbate 60, polyorbate 60, polysorbate 80, polyethylene glycol, purified water, sorbitan monostearate and denatyl alcohol.

Questions? Call 1-866-923-4914

NO VARNISH
ON THIS FLAP

SHOPKO®



MICONAZOLE 3
miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-070
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: WZHBC48M4T)	
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:37012-070-09	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 - Shopko Stores Operating Co., LLC (023252638)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(37012-070)