

MICONAZOLE 7- miconazole nitrate cream
Shopko Stores Operating Co., LLC

Miconazole 7

Drug Facts

Active ingredient (in each applicator)

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 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:
 - **applicators:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Throw away applicator after each 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
 - To open:** unscrew cap, use pointed end on cap to puncture seal
 - To close:** screw cap back onto the tube
- store at 20°-25°C (68°-77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

Apricot Kernel Oil/PEG-6, Butylated Hydroxytoluene, Mineral Oil, PEG-6-32 Stearate/Glycol Stearate, Purified Water and Benzoic Acid (0.20%) as a preservative

Questions?

Call 1-866-923-4914

PRINCIPAL DISPLAY PANEL - 45 g Tube Carton

NDC 37012-035-07

SHOPKO®

Compare to the active ingredient in Monistat® 7

Miconazole 7

Miconazole Nitrate Vaginal Cream USP (2%)

Vaginal Antifungal

(Miconazole Nitrate 100 mg Per Applicator)

7 Day Treatment

Educational Brochure

Enclosed

One 45 g (1.5 oz) Tube Of Miconazole Nitrate Vaginal Cream USP (2%)
& 7 Disposable Applicators

SHOPKO®

7 Day Treatment

Miconazole 7

Miconazole Nitrate Vaginal Cream USP (2%) Vaginal Antifungal
(Miconazole Nitrate 100 mg Per Applicator)

Compare to the active ingredient in Monistat® 7

Cures Most Vaginal Yeast Infections & Relieves Associated External Feminine Itching & Irritation

SHOPKO®

NDC 37012-035-07

Miconazole 7

Miconazole Nitrate Vaginal Cream USP (2%)
Vaginal Antifungal
(Miconazole Nitrate 100 mg Per Applicator)

7 Day Treatment

Compare to the active ingredient in Monistat® 7



Educational Brochure Enclosed

One 45 g (1.5 oz) Tube Of Miconazole Nitrate Vaginal Cream USP (2%) & 7 Disposable Applicators



* This product is not manufactured or distributed by Insight Pharmaceuticals LLC owner of the registered trademark Monistat® 7.

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



By Refund Or Exchange

<p>Apply to itchy, irritated skin outside the vagina (VUVA). Use 2 times daily for up to 7 days as needed.</p> <p>• children under 12 years of age: ask a doctor</p> <p>Other information • do not purchase if carton is opened</p> <p>• do not use if seal over tube opening has been punctured or is not visible</p> <p>To open: unscrew cap, use pointed end on cap to puncture seal</p> <p>To close: screw cap back onto the tube • store at 20°-25°C (68°-77°F)</p> <p>• see carton or tube crimp for lot number and expiration date</p> <p>Inactive ingredients</p> <p>Apricot Kernel Oil/PEG-6, Butylated Hydroxytoluene, Mineral Oil, PEG-6-32 Stearate/Glycol Stearate, Purified Water and Benzoic Acid (0.20%) as a preservative</p> <p>Questions? Call 1-866-923-4914</p>	<p>the pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.</p> <p>• been exposed to the human immunodeficiency virus (HIV) that causes AIDS</p> <p>Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur</p> <p>When using this product</p> <p>• 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)</p> <p>• do not have vaginal intercourse</p> <p>• mild increase in vaginal burning, itching or irritation may occur</p> <p>• if you do not get complete relief ask a doctor before using another product.</p>
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Drug Facts (continued)

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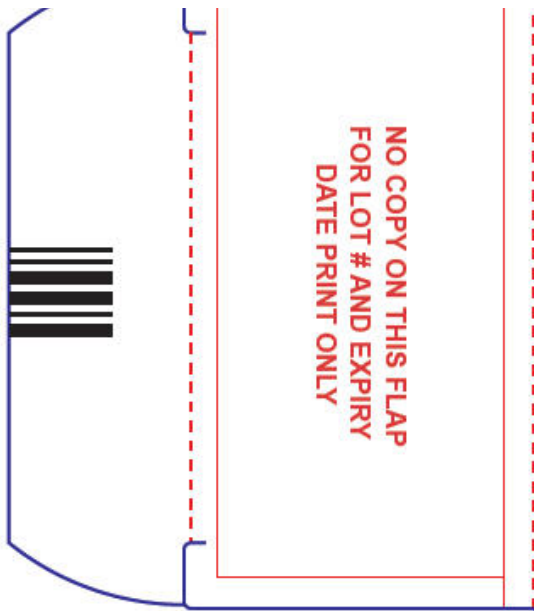
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SHOPKO®

Miconazole 7

Miconazole Nitrate Vaginal Cream USP (2%)
Vaginal Antifungal
(Miconazole Nitrate 100 mg Per Applicator)

7 Day Treatment



MICONAZOLE 7

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-035
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4H1CYW1K) (miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	2 mg in 100 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:37012-035-07	1 in 1 CARTON		
1		45 g in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074444	01/13/1997	

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(370 12-035)

Revised: 4/2014

Shopko Stores Operating Co., LLC