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

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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
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
MICONAZOLE 3
miconazole nitrate cream
**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
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<tbody>
<tr>
<td>Route of Administration</td>
<td>VAGINAL</td>
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<tr>
<td>Item Code (Source)</td>
<td>NDC:37012-070</td>
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**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>Miconazole Nitrate (UNII: VW4H1CYW1K)</td>
<td>Miconazole Nitrate</td>
<td>40 mg in 1 g</td>
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**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>cetyl alcohol (UNII: 936JST6JCN)</td>
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<tr>
<td>isopropyl myristate (UNII: 0RE8K4LNJS)</td>
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<tr>
<td>polysorbate 60 (UNII: CAL22UVI4M)</td>
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<tr>
<td>polysorbate 80 (UNII: 6OZP39ZG8H)</td>
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<tr>
<td>potassium hydroxide (UNII: WZHBCC48M4T)</td>
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<tr>
<td>propylene glycol (UNII: 6DC9Q167V3)</td>
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<tr>
<td>water (UNII: 059QF0KO0R)</td>
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<tr>
<td>sorbitan monostearate (UNII: NVZ40H58X)</td>
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<td>stearyl alcohol (UNII: 2KR8914H1Y)</td>
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**Packaging**

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<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>1</td>
<td>NDC:37012-070-09</td>
<td>1 in 1 CARTON</td>
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</tr>
<tr>
<td>1</td>
<td></td>
<td>25 g in 1 TUBE, WITH APPLICATOR</td>
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**Marketing Information**

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<td>ANDA</td>
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**Labeler** - Shopko Stores Operating Co., LLC (023252638)

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

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
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<th>Business Operations</th>
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<tr>
<td>Taro Pharmaceuticals Inc.</td>
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<td>206263295</td>
<td>MANUFACTURE(37012-070)</td>
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Revised: 4/2014