

SUNMARK CLOTRIMAZOLE 3- clotrimazole cream
Strategic Sourcing Services LLC

sunmark[®]
Clotrimazole 3

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Clotrimazole USP 2% (100 mg in each applicatorful)	Vaginal Antifungal
Clotrimazole USP 2% (external cream)	Vaginal Antifungal

Use

- 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

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 a 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 enclosed educational brochure for complete directions and

information

- adults and children 12 years of age and over:
 - **vaginal cream:** insert one applicatorful of cream into the vagina at bedtime for 3 days in a row. Throw applicator away after use.
 - **external cream:** 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. Use 2 times daily for up to 7 days as needed.
- children under 12 years of age: ask a doctor

Other information

- To open: unscrew cap, use pointed end on cap to puncture seal
- do not use if carton is opened
- **safety sealed:** the tube opening should be sealed. If the seal has been punctured or is not visible, do not use the product.
- store between 20° to 25°C (68° to 77°F)
- see flap of carton or crimp of tube for lot number and expiration date

Inactive ingredients

benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate-60, purified water, and sorbitan monostearate

Questions or comments?

Call toll-free, **1-888-827-6222**, for our 24 hour automated response system.

Distributed by McKesson
One Post Street
San Francisco, CA 94104

PRINCIPAL DISPLAY PANEL - 21 g Tube Carton

sunmark®

clotrimazole 3

Clotrimazole Vaginal Cream USP (2%)

Vaginal Antifungal

Cures Most Vaginal Yeast Infections

3 DAY TREATMENT

**One 21 g (0.74 oz) Tube Of Clotrimazole Vaginal Cream USP (2%)
& 3 Disposable Applicators**

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-379
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
benzyl alcohol (UNII: LKG8494WBH)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetyl esters wax (UNII: D072FFP9GU)	
octyldodecanol (UNII: 461N1O614Y)	
poly sorbate 60 (UNII: CAL22UVI4M)	
water (UNII: 059QF0KO0R)	
sorbitan monostearate (UNII: NVZ4I0H58X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-379-54	1 in 1 CARTON	02/12/2013	
1		21 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
NDA	NDA021143	04/12/2000	

Labeler - Strategic Sourcing Services LLC (116956644)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(49348-379)