

SUNMARK CLOTRIMAZOLE 3- clotrimazole cream
McKesson

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**

sunmark®

NDC 49348-379-54



Cures Most Vaginal Yeast Infections

3 DAY TREATMENT

Educational Brochure Enclosed

LPK-4628-2
0912-2
MH52

1752

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

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

sunmark®
clotrimazole 3
Clotrimazole Vaginal
Cream USP (2%)
Vaginal Antifungal



T128B
5851T

Drug Facts (continued)
Other Information • To open: unscrew cap, use pointed end on cap to puncture seal.
• do not use if cap or is cracked.
• safety seal has the following number and date: 1752
• store between 20° to 25°C (68° to 77°F).
• see flap of carton or amp of tube for lot number and expiration date.
Inactive ingredients benzyl alcohol, octylalanyl alcohol, octylalanyl alcohol, polyethylene glycol, purified water, and sodium monoborate.
Questions or comments? Call toll-free, 1-800-877-4222, for our 24-hour automated response system.

MCKESSON
Another Quality Product
Distributed by McKesson
One First Street
San Francisco, CA 94104
Money Back Guarantee
Please visit us at
www.sunmarkbrand.com
Made in Canada.

NO VARNISH
ON THIS FLAP

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Drug Facts
Active Ingredients Clotrimazole USP 2% (100 mg in each applicator/amp).
Clotrimazole USP 2% (external cream).
Vaginal Antifungal
Purpose
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 be on 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 during treatment.
• mild increase in vaginal burning, itching or irritation may occur.
Stop use and ask a doctor if
• if you do not get completely better after 3 days.
• if you do not get completely better after 7 days.
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 breastfeeding, ask a health professional before use.
If pregnant or breastfeeding, ask a health professional before use.
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 applicator of cream into the vagina at bedtime for 3 days in a row. Throw applicator away after use or into your toilet. Apply to dry, itchy skin outside the vagina. Squares a small amount of cream to your finger. Apply to dry, itchy skin outside the vagina. Use 2 times daily for up to 7 days as needed.
• children under 12 years of age: ask a doctor
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

SUNMARK CLOTRIMAZOLE 3
clotrimazole cream

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		
1		21 g in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021143	04/12/2000	

Labeler - McKesson (177667227)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

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