

SUNMARK CLOTRIMAZOLE 3- clotrimazole cream
Strategic Sourcing Services LLC

sunmark®
Clotrimazole 3

Drug Facts

Active ingredients	Purpose
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

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One 21 g (0.74 oz) Tube Of Clotrimazole Vaginal Cream USP (2%)
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sunmark®

clotrimazole 3

Clotrimazole Vaginal
Cream USP (2%)
Vaginal Antifungal

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



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5851T

Drug Facts (continued)

Other Information • Topical, unswallow cap, use pointed end on cap to puncture seal.

• do not use if cap or is opened.

• safety see lot the this opening should be sealed. If the seal has been punctured or is not sealed, do not use the product.

• 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, 1-800-827-4222, for our 24-hour automated response system.

Drug Facts

Active Ingredients Clotrimazole USP 2% (100 mg in each applicator/insertion).

Purpose 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 be in 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 using another product.
- 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.

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 reuse only your finger. Apply to every applicator and insert into the vagina. Squares a small amount of cream onto your finger.
- external cream: insert applicator into the vagina and apply the cream to the skin outside the vagina. Squares a small amount of cream onto your finger. Apply to every applicator and insert into the vagina. Use 2 times daily for up to 7 days as needed.

• children under 12 years of age: ask a doctor

MESSESSON

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

NO VARNISH
ON THIS FLAP

NO VARNISH
ON THIS FLAP

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)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0K00R)	
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	10/31/2026
1		21 g in 1 TUBE, WTH 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	10/31/2026

Labeler - Strategic Sourcing Services LLC (116956644)**Establishment**

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(49348-379)