

**CLOTRIMAZOLE- clotrimazole cream
STRATEGIC SOURCING SERVICES LLC**

Clotrimazole Vaginal Cream USP 1%

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Clotrimazole USP 1% (50 mg in each applicatorful)	Vaginal antifungal
Clotrimazole USP 1% (external cream)	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

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 7 days in a row. Wash applicator after each 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

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

Questions or comments?

call **833-358-6431**

Distributed by: McKesson Corp.,
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Memphis, TN 38141

PRINCIPAL DISPLAY PANEL - 45 g Tube Carton

Foster & Thrive™

7 DAY TREATMENT

7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP 1%
VAGINAL ANTIFUNGAL

Cures Most Vaginal Yeast Infections

- Educational Brochure Enclosed

One 45 g (1.5 oz) Tube of Clotrimazole Vaginal Cream USP 1% & 1 Reusable Applicator

NDC 70677-1262-1

Foster & Thrive™

7 DAY TREATMENT

7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP 1%
VAGINAL ANTIFUNGAL

NET WT 45 g (1.5 oz)

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1024
34

NO VARNISH/ NO AQ
NO COPY/ NO COLOR
THIS FLAP FOR LOT #
AND EXP DATE PRINT

Foster & Thrive™

7 DAY TREATMENT

7 Day Vaginal Cream

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VAGINAL ANTIFUNGAL

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Foster & Thrive™

7 DAY TREATMENT

7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP 1%
VAGINAL ANTIFUNGAL

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Money Back Guarantee
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Product of Canada
Rev. 10/2024

NO VARNISH
ON THIS FLAP

NO VARNISH
ON THIS FLAP

Drug Facts

Active Ingredients
Clotrimazole USP 1% (50 mg in each applicator), Vaginal antifungal

Purpose
• you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or a foul-smelling vaginal discharge
• Vaginal cream: insert one applicator of cream into the vagina at bedtime for 7 days in a row. Wash applicator after each 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.

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 7 days in a row. Wash applicator after each 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.

Other information
• do not use if carton is opened
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• store between 20° to 25°C (68° to 77°F)
• see flap of carton or comp of tube for lot number and expiration date

Inactive ingredients
2-octyldodecanol, benzyl alcohol, cetylstearyl alcohol, cetyl esters wax, polyoxylate 60, purified water, sorbitan monooleate

Questions or comments? call 833-358-6431

Drug Facts (continued)

Warnings
Do not use if you have never had a vaginal yeast infection diagnosed by a doctor
For vaginal use only

Uses
• treats vaginal yeast infections
• relieves external itching and irritation due to a vaginal yeast infection

Stop use and ask a doctor if
• symptoms do not get better in 3 days
• symptoms last more than 7 days

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
• 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 before use if you have
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• lower abdominal, back or shoulder pain, fever, chills, nausea,
• vaginal yeast infection often (such as once a month or 3 in 6 months).
• you may have a more serious condition.

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Clotrimazole Vaginal Cream USP 1%
VAGINAL ANTIFUNGAL

CLOTRIMAZOLE
clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1262
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1262-1	1 in 1 CARTON	11/07/2024	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072641	11/07/2024	

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(70677-1262)