

CLOTRIMAZOLE- clotrimazole cream
Foster and Thrive (Mckesson /STRATEGIC SOURCING SERVICES LLC)

Clotrimazole

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

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 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?

call **833-358-6431** Monday to Friday 9:00am to 7:00pm EST

Distributed by: McKesson Corp.,
via Strategic Sourcing Services LLC.
Memphis, TN 38141

PRINCIPAL DISPLAY PANEL - 21 g Tube Carton

Foster & Thrive™

Clotrimazole 3

Clotrimazole Vaginal Cream USP 2%
VAGINAL ANTIFUNGAL

3 Day Treatment • Cures Most Vaginal Yeast Infections

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

Educational
Brochure
Enclosed

(COLOUR BLEED LINE)

NDC 70677-1231-1

Foster & Thrive™

Clotrimazole 3

Clotrimazole Vaginal Cream USP 2%
VAGINAL ANTIFUNGAL

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Foster & Thrive™

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Clotrimazole 3

Clotrimazole Vaginal Cream USP 2%
VAGINAL ANTIFUNGAL

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

T1285
B813
ENG19.33



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Pharmaceutical
Read Direction

NO VARNISH
ON THIS FLAP

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ON THIS FLAP

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Purpose	• relieves external itching and irritation due to a vaginal yeast infection
Uses	• 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 other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).
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).
Stop use and ask a doctor if	• symptoms do not get better in 3 days • symptoms last more than 7 days
Questions?	call 833-358-6431 Monday to Friday 9:00am to 7:00pm EST
Drug Facts (continued)	
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
• vaginal cream:	insert 1 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.
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• see flap of carton or crimp of tube for lot number and expiration date	
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CLOTRIMAZOLE
clotrimazole cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1231	
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: 059QF0KO0R)				
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1231-1	1 in 1 CARTON	10/05/2023	
1		21 g in 1 TUBE, WTH APPLICATOR; Type 1: Convenience Kit of Co-Package		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NDA	NDA021143		10/05/2023	

Labeler - Foster and Thrive (Mckesson /STRATEGIC SOURCING SERVICES LLC) (116956644)

Establishment			
Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(70677-1231)