

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

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**Clotrimazole**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
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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Educational  
Brochure  
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Foster & Thrive™

# Clotrimazole 3

Clotrimazole Vaginal Cream USP 2%  
VAGINAL ANTIFUNGAL

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



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Pharmaceutical  
Read Direction

NO VARNISH  
ON THIS FLAP

NO VARNISH  
ON THIS FLAP

**Drug Facts**

**Clotrimazole 3**  
Clotrimazole Vaginal Cream USP 2%  
VAGINAL ANTIFUNGAL

**Purpose**  
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  
• low 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).  
• 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).

**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).  
• been exposed to the human immunodeficiency virus (HIV) that causes AIDS

**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)**  
• 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 8 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**  
• do not use if cap is opened.  
• to open: unscrew cap, use pointed end on cap to puncture seal  
safely 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, cetoesteranyl alcohol, cetyl esters wax, 2-octyldodecanol,  
polyorbene-60, purified water, and sorbitan monoesterate

**CLOTRIMAZOLE**  
clotrimazole cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-1231
<b>Route of Administration</b>	VAGINAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CLOTRIMAZOLE</b> (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	2 g in 100 g

**Inactive Ingredients**

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

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA021143	10/05/2023	

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

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Taro Pharmaceuticals Inc.		206263295	manufacture(70677-1231)

Revised: 1/2024

Foster and Thrive (Mckesson /STRATEGIC SOURCING SERVICES LLC)