

**CLOTRIMAZOLE- clotrimazole cream**  
**Preferred Pharmaceuticals, Inc.**

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**Clotrimazole**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
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**

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

## **Questions or comments?**

call **1-866-923-4914**

Distributed by:

**Taro Pharmaceuticals U.S.A., Inc.**

Hawthorne, NY 10532

**Relabeled By: Preferred Pharmaceuticals Inc.**

**PRINCIPAL DISPLAY PANEL - 45 g Tube Carton**

Cures Most Vaginal Yeast Infections  
**7 Day Treatment**

**7 Day Vaginal Cream**

**Clotrimazole Vaginal Cream USP (1%)  
 Vaginal Antifungal**

NDC 68788-9665-4

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

**Educational Brochure Enclosed**

**Clotrimazole 7 Vaginal Cream**  
 Generic for Gyne-Lotrimin  
 Active ingredient(in each applicator):  
 Clotrimazole,USP 50mg(1%).....Vaginal  
 Antifungal/External Vulvar Antifungal  
**Pkg Size:** Exp Date: #####/####/####  
 Ins:  
 Mfg: H2-Pharma, LLC  
 Prod#:  
**Warning**  
For vaginal use only. Do not use if you have never had a vaginal yeast infection diagnosed by a doctor. Store between 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). Keep out of reach of children. See box for uses, warnings, directions, and other information.



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed.

Clotrimazole 7 Vaginal Cream  
 Qty: Ins:  
 Lot: Bat:  
 Prod# (NDC):



Directions English  
 Use as directed on package.



GTIN  
 #####/#####  
 SN #####  
 EXP #####/#####

Instrucciones Espanol:  
 Utilice como dirigido en el paquete.

Clotrimazole 7 Vaginal Cream  
 Qty: Ins:  
 Lot: Bat:  
 Prod# (NDC):

Chart

Clotrimazole 7 Vaginal Cream  
 Qty: Ins:  
 Insurance NDC:  
 Lot: Bat:

Billing

Clotrimazole 7 Vaginal Cream  
 Qty: Ins:  
 Lot: Bat:  
 Prod# (NDC):

Patient

<b>CLOTRIMAZOLE</b> clotrimazole cream			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68788-9665(NDC:51672-2003)
<b>Route of Administration</b>	VAGINAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
<b>Clotrimazole</b> (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	1 g	in 100 g
Inactive Ingredients			
	Ingredient Name	Strength	
<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)			

**water** (UNII: 059QF0KO0R)

**sorbitan monostearate** (UNII: NVZ4I0H58X)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-9665-4	1 in 1 CARTON	08/05/2013	
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	08/05/2013	

**Labeler** - Preferred Pharmaceuticals, Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals, Inc. (791119022)

### Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	RELABEL(68788-9665)

Revised: 3/2025

Preferred Pharmaceuticals, Inc.