

**CLOTRIMAZOLE- clotrimazole cream**  
**Taro Pharmaceuticals U.S.A., 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

## **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**

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

**Educational Brochure Enclosed**

NDC 51672-2003-6

Compare to the active ingredient in Gyne-Lotrimin® 7\*

7 Day Treatment

# 7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (1%)  
Vaginal Antifungal



Cures Most Vaginal Yeast Infections

# 7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (1%)  
Vaginal Antifungal

7 Day Treatment

LPK-1314-7  
0915-7  
M67

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

Cures Most Vaginal Yeast Infections

# 7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (1%)  
Vaginal Antifungal

7 Day Treatment

One 45 g (1.5 oz) Tube Of Clotrimazole Vaginal Cream USP (1%)  
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Cures Most Vaginal Yeast Infections  
**7 Day Vaginal Cream**  
Clotrimazole Vaginal Cream USP (1%)  
Vaginal Antifungal  
7 Day Treatment

TT288  
B81.3  
ENGL19.33



\* This product is not manufactured or distributed by MSD Consumer Care Inc., a subsidiary of Merck & Co., Inc.



Distributed by:  
Taro Pharmaceuticals U.S.A., Inc.  
Hawthorne, NY 10532  
Made in Canada

NO VARNISH  
ON THIS FLAP

NO VARNISH  
ON THIS FLAP

**Drug Facts**

**Active Ingredients**  
Clotrimazole USP 1% (50 mg in each applicatorful)..... Vaginal antifungal

**Purpose**  
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

**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 fall to prevent pregnancy or sexually transmitted diseases (STDs).  
• If you do not get complete relief or if symptoms do not get better in 3 days, stop use and ask a doctor if:  
• symptoms last more than 7 days  
• symptoms do not get better in 3 days

**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 of cream 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: uncrew cap, use pointed end on cap to puncture seal.  
• do not use if carton is opened  
• do not use if seal has been punctured or is not visible, do not use the product.  
• see flap of carton or crimp of tube for lot number and expiration date

**Inactive Ingredients**  
polyorbate 60, purified water, sorbitan monostearate, benzyl alcohol, octylsteary alcohol, oleyl esters wax, 2-oxydodecanol.

**Questions or comments?** call 1-866-923-1914

7 Day Treatment

Clotrimazole Vaginal Cream USP (1%)  
Vaginal Antifungal

# 7 Day Vaginal Cream

Cures Most Vaginal Yeast Infections

## CLOTRIMAZOLE

clotrimazole cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2003	
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		
	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:51672-2003-6	1 in 1 CARTON	12/04/1995	
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	12/04/1995		

**Labeler** - Taro Pharmaceuticals U.S.A., Inc. (145186370)

### Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2003)

Revised: 1/2019

Taro Pharmaceuticals U.S.A., Inc.