

# **CLOTRIMAZOLE- clotrimazole cream**

## **A-S Medication Solutions**

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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

### **HOW SUPPLIED**

Product: 50090-0614

NDC: 50090-0614-0 45 g in a TUBE / 1 in a CARTON

### **Clotrimazole**



## CLOTRIMAZOLE

clotrimazole cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-0614(NDC:51672-2003)
<b>Route of Administration</b>	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:50090-0614-0	1 in 1 CARTON	11/28/2014	
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** - A-S Medication Solutions (830016429)

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-0614)

Revised: 2/2023

A-S Medication Solutions