

CLOTRIMAZOLE- clotrimazole cream
Preferred Pharmaceuticals, Inc.

Clotrimazole Vaginal Cream

Drug Facts

Active ingredients

Clotrimazole 1% (50 mg in each applicatorful)

Clotrimazole 1% (external cream)

Purpose

Vaginal antifungal

Vaginal antifungal

Uses

- treats vaginal yeast infections
- relieves external itching and irritation associated 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 (1-800-222-1222) 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

- store at room temperature between 2° and 30°C (36° to 86°F)
- see end flaps of carton and tube for lot number and expiration date
- **Tamper-evident: Safety sealed:** the tube opening should be sealed. If seal has been punctured or is not visible, do not use the product.

Inactive ingredients

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

Questions?

1-800-432-8534 between 9 am and 4 pm EST, Monday- Friday.

Principal Display Panel

45g tube - 68788-0169-4

Compare to the active ingredient
in Gyne-Lotrimin® Vaginal Cream*

Clotrimazole
Vaginal Cream, USP 1%

Vaginal Antifungal
Cures Most Vaginal Yeast Infections
1 Reusable Applicator (7-Day Therapy)
7-Day Treatment

ONE 45 g (1.5 OZ) Tube of Vaginal Cream (1%) and

1 Reusable Applicator (7-Day Therapy)

Educational Pamphlet Enclosed

Clotrimazole 7 Vaginal Cream
 Generic for: Gyne-Lotrimin
 Active ingredient (in each applicator):
 Clotrimazole USP 50mg(1%).....Vaginal
 Antifungal/External Vulvar Antifungal

PREFERRED
 Pharmaceuticals, Inc.
 The Physician's Solution. Anaheim, Ca

Pkg Size: Exp Date:
 Lot#: Batch#:
 Ins:
 Mfg: Actavis MidAtlantic LLC, Lincolnton,
 NC
 Prod#:

Warning
 For vaginal or external vulvar use only. Store between 7° and 30°C (36° 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):

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

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

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

Log

Chart

Billing

Patient

Use as directed on package.

Directions English

Instrucciones Espanol:
 Utilice como dirigido en el paquete.

CLOTRIMAZOLE				
clotrimazole cream				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-0169(NDC:0472-0220)	
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: 059QF0K00R)				
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)				
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-0169-4	1 in 1 CARTON	08/06/2013	
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	ANDA074165	08/06/2013	

Labeler - Preferred Pharmaceuticals, Inc. (791119022)

Registrant - Preferred Pharmaceuticals, Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	RELABEL(68788-0169)

Revised: 6/2017

Preferred Pharmaceuticals, Inc.