CLOTRIMAZOLE- clotrimazole cream
Preferred Pharmaceuticals Inc.

Clotrimazole

Drug Facts

Active ingredients	***Purpose***
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 (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

- to open tube: unscrew cap, lift tab, and pull to remove foil seal prior to use
- do not use if foil seal on tube opening is broken or missing
- do not purchase if carton is open
- store at room temperature 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F)
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

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

Questions?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Distributed by: **H2-Pharma, LLC**
Montgomery, AL 36117
www.h2-pharma.com

Relabeled By: Preferred Pharmaceuticals Inc.

PRINCIPAL DISPLAY PANEL - 45 g Tube Carton

NDC 668788-8491-4

Clotrimazole
Vaginal Cream, USP 1%

Vaginal Antifungal
(with 1 Reusable Applicator)

Cures most vaginal yeast infections
7-day therapy / 7-day treatment
Educational pamphlet enclosed

Net wt. 1.59 oz (45 g) tube

7 day vaginal cream with 1 reusable applicator

H^2 pharma

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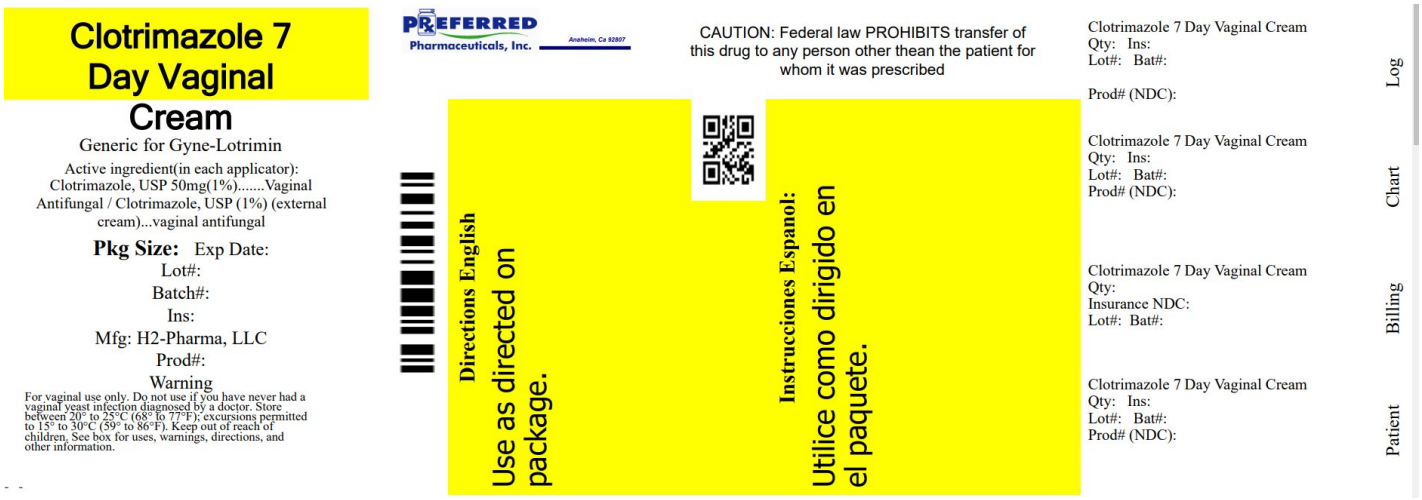

CLOTRIMAZOLE

clotrimazole cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68788-8491(NDC:61269-220)
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 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)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8491-4	1 in 1 CARTON	07/24/2023	
1		45 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074165	07/24/2023	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8491)

Revised: 4/2024 Preferred Pharmaceuticals Inc.