CLOTRIMAZOLE- clotrimazole cream NuCare 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 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

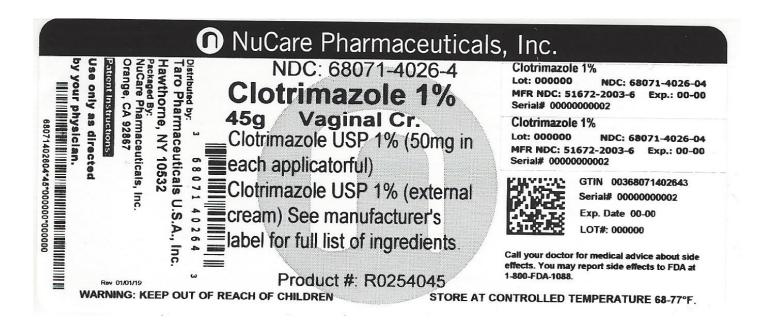
benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sorbitan monostearate

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



CLOTRIMAZ	-						
clotrimazole crea	m						
Product Infor	mation						
Product Type		HUMAN OTC DRUG	Item Code (Sou	rce) NE	DC:68071-4	4026(NDC	51672-2003)
Route of Admini	stration	VAGINAL					
Active Ingredi		-					
Ingredient Name Basis of St			trength	-			
CLOTRIMAZOLE (U	CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65) CLOTRIMAZOLE				E	1 g in 100 g	
Inactive Ingre	dients						
indecive ingre	alents	Ingradiant Na	mo			C+	ronath
Ingredient Name BENZYL ALCOHOL (UNII: LKG8494WBH)					51	Strength	
CETOSTEARYL ALCOHOL							
CETYL ESTERS WA							
OCTYLDODECANO							
POLYSORBATE 60	(UNII: CAL22UV	/I4M)					
WATER (UNII: 059Q	F0KO0R)						
SORBITAN MONOS	TEARATE (UN	II: NVZ4I0H58X)					
Packaging							
# Item Code	Pac	ckage Description	on Ma	rketing Date	Start		eting End Date
1 NDC:68071-	1 in 1 CARTON	J	07/22/	2020			
4026-4							

Marketing Information							
Marketing Category			Marketing End Date				
ANDA	ANDA072641	12/04/1995					

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment						
Name	Address	ID/FEI	Business Operations			
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-4026)			

Revised: 7/2024

NuCare Pharmaceuticals, Inc.