

CLOTRIMAZOLE- clotrimazole cream
NuCare Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Perrigo Clotrimazole Cream USP, 1% Drug Facts

Active ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

- cures most athlete's foot, jock itch and ringworm
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions

Warnings

For external use only

Do not use

on children under 2 years of age unless directed by a doctor

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- wash the affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)

- supervise children in the use of this product
- for athlete's foot pay special attention to the spaces between the toes, wear well-fitting ventilated shoes and change shoes and socks at least once daily
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition persists longer, consult a doctor
- this product is not effective on the scalp or nails

Other information

- store at 20°-25°C (68°-77°F)


Inactive ingredients

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

Questions or comments?

1-800-719-9260

Principal Display Panel


NuCare Pharmaceuticals, Inc.

NDC: 68071-3395-3

Clotrimazole 1%


1oz Cream

See manufacturer's label for full list of ingredients.

Product #: R0255030

Clotrimazole 1%
 Lot: 000000 NDC: 68071-3395-03
 MFR NDC: 45802-434-11 Exp.: 00-00

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 MFR NDC: 45802-434-11 Exp.: 00-00



GTIN 00368071339536
 Serial# 00000000002
 Exp. Date 00-00
 LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Packaged By:
 NuCare Pharmaceuticals, Inc.
 Orange, CA 92867

Distributed by:
 Perrigo Allegan, MI 49010

Apply every _____ hours
 times a day.

68071339503*1oz*000000*000000

Rev 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

CLOTRIMAZOLE

clotrimazole cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-3395(NDC:45802-434)
Route of Administration	TOPICAL		

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:68071-3395-3	30 g in 1 BOX; Type 0: Not a Combination Product	07/12/2017	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part333C	06/03/2011	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment			
Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-3395)

Revised: 2/2021

NuCare Pharmaceuticals, Inc.