

MAJOR CLOTRIMAZOLE- clotrimazole cream
Central Texas Community Health Centers

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.

Major Clotrimazole

Drug Facts

Active ingredient

Clotrimazole USP 1% w/w

Purpose

Antifungal Cream

Uses

Cures athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis). Relieves the itching, irritation, redness, scaling and discomfort which can accompany these conditions.

Warnings

- **Do not use on children under 2 years of age unless directed by a doctor.**
- **For external use only.**
- **Avoid contact with eyes.**
- If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch), discontinue use and consult a doctor.
- **Keep this and all drugs out of the reach of children.**

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

- Clean the affected area and dry thoroughly.
- Apply a thin layer of this product over affected area twice daily (morning and night), or as directed by a doctor.
- 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 conditions persists longer, consult a doctor.
- This product is not effective on the scalp or nails.

Other information

- Store at controlled room temperature 15°-30°C (59°-86°F).
- Close cap tightly after use.

Inactive ingredients

aloe vera, benzyl alcohol, cetearyl alcohol, 2-octyldodecanol, polysorbate 60, sorbitan monostearate, spermwax, vitamin E, water

Questions?

Adverse Drug Event call (800)616-2471
Dist. By MAJOR PHARMACEUTICALS
31778 Enterprise Drive, Livonia, MI 48150 USA
Re-Order No. 100431

Principal Display Panel - 15 g Tube Label

CommUnityCare Federally Qualified Health Centers

Clotrimazole

1%

TOPICAL

Cream

Date:

Name:

Dr.

USE AS DIRECTED.

123456

1/1/01

Clotrimazole 1% TOPICAL Cream 15g NDC 76413-304-15

Batch: 123456

Lot: 123456

Exp: 1/1/01

MAJOR

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

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MAJOR CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-304(NDC:0904-7822)
Route of Administration	TOPICAL		

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
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:76413-304-15	1 in 1 CARTON		
1		14.17 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	
OTC monograph final	part333C	10/04/2004		

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-304) , RELABEL(76413-304)

Revised: 3/2016

Central Texas Community Health Centers