

MAJOR CLOTRIMAZOLE- clotrimazole cream

Proficient Rx LP

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

Relabeled By Proficient Rx LP
Thousand Oaks, CA 91320

Re-Order No. 100431





Principal Display Panel - ½ oz. Tube

NDC 71205-438-05

CLOTRIMAZOLE ANTI-FUNGAL CREAM

CREAM USP, 1%

Cures Most Athlete's Foot NET WT. 14.17 g (1/2oz)

	<p>Scan Here</p> 	<p>NDC 71205-438-05</p>	<p>Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320</p>
<p>3 7 1 2 0 5 4 3 8 0 5 0</p> 	<h1>Clotrimazole 1%</h1> <p>14.17 g (1/2oz) Cream</p>		<p>Clotrimazole 1% 14.17 g (1/2oz) Cream Lot #:00000 SN# MASTER NDC 71205-438-05 Exp:00/00/00</p>
	<p>Each tube contains: Clotrimazole USP 1% w/w Antifungal Cream</p>		<p>Clotrimazole 1% 14.17 g (1/2oz) Cream Lot #:00000 SN# MASTER NDC 71205-438-05 Exp:00/00/00</p>
	<p>See box</p>	<p>For external use only</p>	<p>Clotrimazole 1% 14.17 g (1/2oz) Cream Lot #:00000 SN# MASTER NDC 71205-438-05 Exp:00/00/00</p>
	<p>Product ID: SC043805</p>		 <p>GTIN: 00371205438050 SN# MASTER Exp. 00/00/00 Lot #:00000</p>
	<p>Dist. By: MAJOR PHARMACEUTICALS 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA</p>		
	<p>Store at controlled room temperature 20°-25°C (68° - 77°F)</p>		
		<p>Keep medication out of the reach of children</p>	

MAJOR CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71205-438(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: 2DMT128M1S)	
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
1	NDC:71205-438-05	1 in 1 CARTON	07/02/2020	
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 Drug	M005	10/04/2004	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-438) , RELABEL(71205-438)

