

MAJOR CLOTRIMAZOLE- clotrimazole cream

Major Pharmaceuticals

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.

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 – 1 oz. Tube

MAJOR® NDC 0904-7822-31

CLOTRIMAZOLE ANTI-FUNGAL CREAM

CREAM USP, 1%

Cures Most Athlete's Foot NET WT. 28.35 g (1 oz)

The image shows the principal display panel for MAJOR CLOTRIMAZOLE ANTI-FUNGAL CREAM USP, 1%. The panel is rectangular with a white background and a grey header section. The header contains the MAJOR logo (a stylized 'M' inside a circle) and the NDC number 0904-7822-31. Below the logo, the product name 'CLOTRIMAZOLE' is written in large, bold, black letters, followed by 'ANTI-FUNGAL CREAM' in smaller, orange letters. Below that, 'CREAM USP, 1%' is written in orange. The phrase 'Cures Most Athlete's Foot' is written in orange, and 'NET WT. 28.35 g (1 oz)' is written in grey. The main body of the panel contains the following text:
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.
See carton for complete adverse effects reporting information.
Dist. by: Major Pharmaceuticals, 31778 Enterprise Drive, Livonia, MI 48150 USA
Manufactured in USA Reorder No. 100431 M-101
A barcode is located at the bottom right of the panel, with the numbers 09047 82231 7 printed below it. To the right of the panel, there are two black rectangular bars, one above the other. The number 232614 is printed vertically on the right edge of the panel.

Principal Display Panel – 1 oz. Carton

MAJOR® NDC 0904-7822-31

Cures Most

Athlete's Foot

Relieves Itching, Burning, Greaseless, Nonstaining

CLOTRIMAZOLE ANTI-FUNGAL CREAM

CREAM USP, 1%

*Compare To the active ingredient in Lotrimin-AF® NET WT. 28.35 g (1 oz)



NDC 0904-7822-31

Cures Most Athlete's Foot

Relieves Itching, Burning, Greaseless, Nonstaining

CLOTRIMAZOLE

CREAM USP, 1%

*Compare To the active ingredient in Lotrimin-AF®

ANTI-FUNGAL CREAM

NET WT. 28.35 g (1 oz)



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Major® Clotrimazole Anti-Fungal Cream is not manufactured or distributed by Schering-Plough HealthCare Products, Inc. owners of the registered trademark Lotrimin-AF®.

M-101 Rev. 9/08 Manufactured in USA



A549

DRUG FACTS

Active ingredient
Clotrimazole USP 1% w/w Antifungal Cream

Purpose
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Use
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.

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• Clean the affected area and dry thoroughly.

DRUG FACTS (continued)

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

Inactive ingredients
polyorbate 60, sorbitan monostearate, spermwax, vitamin E, water, aloe vera, benzyl alcohol, cetearyl alcohol, 2-octyldodecanol.

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

508836



Relieves Itching and Burning
Greaseless, Nonstaining

Cures Most Athlete's Foot

CLOTRIMAZOLE ANTI-FUNGAL CREAM USP, 1%

MAJOR CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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
1	NDC:0904-7822-31	1 in 1 CARTON	10/04/2004	
1		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0904-7822-36	1 in 1 CARTON	10/04/2004	
2		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 - Major Pharmaceuticals (191427277)

Revised: 1/2021

Major Pharmaceuticals