

HC MAX FOR ATHLETES FOOT- tolnaftate ointment
Kramer Laboratories

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	Purpose
Tolnaftate 1%	Anti-fungal

Uses ■ Proven effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis).
■ Helps prevent most athlete's foot with daily use. ■ For effective relief of itching, burning and cracking.

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 eyes.

Stop use and ask a doctor if ■ Irritation occurs. ■ There is no improvement within 4 weeks.

Keep this and all medication out of the reach of children.

In case of accidental ingestion, contact a physician, emergency medical care facility or Poison Control Center immediately for advice.

Directions ■ Clean affected area with soap and warm water and dry thoroughly. ■ Apply a thin layer of HC Max™ Anti-Fungal Ointment over affected area twice daily (morning and night) or as directed by a doctor. ■ Wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. ■ For athlete's foot pay special attention to spaces between the toes. ■ For athlete's foot and ringworm, use daily for 4 weeks. ■ To prevent athlete's foot, clean the feet and dry thoroughly. Apply a thin layer of the product to the feet once or twice daily (morning and/or night). If condition persists longer, consult a doctor. ■ This product is not effective on the scalp or nails. ■ Supervise children in the use of this product.

Other information Store at controlled room temperature 15°-30° C (59°-86°F) Do not permit to freeze.

Inactive ingredients Purified Water USP, Carbomer Homopolymer Type A (Allyl Pentaerythritol Crosslinked), Phenoxyethanol, Dimethicone 350, Glyceryl Monostearate, Poloxamer 188, Aloe Vera Leaf, Eucalyptol, Lavender Oil, Olive Oil, Tea Tree Oil, Sodium Hydroxide.

PRINCIPAL DISPLAY PANEL

Maximum Strength / Máxima Potencia

HC MAX™

Anti-Fungal Ointment / Ungüento Anti-Hongos

FOR ATHLETE'S FOOT

Cures AND Prevents Most Athlete's Foot
Relives: □ Itching □ Burning □ Cracking

Cura Y Previene La Mayoría de Casos De Pie De Atleta
Alivia: □ Picazón □ Ardor □ Agrietamiento

Maximum Strength / Máxima Potencia

HC MAX™
Tolnaftate 1%

plus
Aloe & Tea Tree Oil
for skin health

CLINICALLY PROVEN INGREDIENT

FOR ATHLETE'S FOOT

NET WT 1 OZ (28gm)

KRAMER
LABORATORIES

Distributed by:
Kramer Laboratories Inc. Bridgewater, NJ 08807
1-800-824-4894

K1219

Maximum Strength / Máxima Potencia

HC MAX™

Anti-Fungal Ointment / Ungüento Anti-Hongos

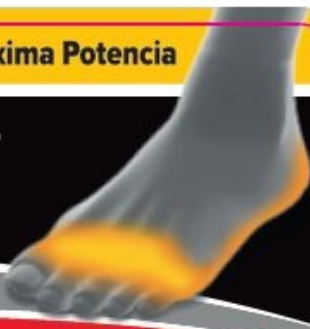
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Inactive ingredients Purified Water USP, Carbonic Anhydrase, Poloxamer 188, Aloe Vera Leaf, Croscellose, Phenoxymethyl Dimethylamine 550, Citronellol, Hydroxyacetone, Poloxamer 188, Aloe Vera Leaf, Eucalyptol, Lavender Oil, Olive Oil, Tea Tree Oil, Sodium Hydroxide.

Maximum Strength / Máxima Potencia

HC MAX™ FOR ATHLETE'S FOOT

Anti-Fungal Ointment / Ungüento Anti-Hongos
Tolnaftate 1%

NET CONTENT 1 OZ. (28g)



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HC MAX FOR ATHLETES FOOT

tolnaftate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55505-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Tolnaftate (UNII: 06KB629TKV) (Tolnaftate - UNII:06KB629TKV)	Tolnaftate	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Carbomer Homopolymer Type A (Allyl Pentaerythritol Crosslinked) (UNII: F68VH75CJC)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Dimethicone 350 (UNII: 2Y53S6ATLU)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Poloxamer 188 (UNII: LQA7B6G8JG)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Eucalyptol (UNII: RV6J6604TK)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Olive Oil (UNII: 6UYK2W1W1E)	
Tea Tree Oil (UNII: VIF565UC2G)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55505-203-26	1 in 1 CARTON	05/13/2020	
1		28 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	05/13/2020	

Labeler - Kramer Laboratories (122720675)**Establishment**

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals		001207208	manufacture(55505-203)