FUNGISTAT MAX- clotrimazole transdermal liquid liquid Bio-Medical & Pharmaceutical Manufacturing Corporation

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

Fungistat topical antifungal liquid.

Active Ingredient

Clotrimazole 1.0%

Purpose

Antifungal

Indications

- Cures most tinea pedis (athlete's foot), tinea cruris (jock itch), and tinea corporis (ringworm).
- Relieves itching, burning feet and itching, scaling, cracking, burning, redness, soreness, irritation, discomfort, and chafing associated with jock itch.
- Clears up most athlete's foot infection and with daily use helps keep it from coming back.

Warnings

- Do not use on children under 2 years of age unless directed by a doctor.
- For external use only.
- Avoid contact with the eyes.
- For Athlete's Foot: If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor.
- For Jock Itch: If irritation occurs or if there is no improvement within 2 weeks, discontinue use and consult a doctor.
- Do not use for diaper rash.
- Flammable Do not use near open flame or heat source.

Keep Out Of Reach Of Children

Directions

- Wash the affected area and dry thoroughly.
- Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor.
- The brush applicator allows easy application under the nails and surrounding cuticle area.
- Always use well-ventilated shoes and change socks at least once each day.
- 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 changes shoes and socks at least once daily.
- For Athlete's Foot & Ringworm: Use daily for 4 weeks.
- If condition persists longer, consult a doctor.

• This product is not effective on the scalp or nails.

Inactive Ingredients

Water, Isopropyl Alcohol, Polysorbate 80, Arnica Montana, Methyl Ethyl Ketone, Sodium Lauryl Sulfate, Undecylenic Acid, Peppermint Oil, Salicylic Acid, Sodium Propionate, Sorbic Acid, Propionic Acid, Thymol, Aloe Vera Leaf.

Questions or Comments

Bio-Medical & Pharmaceutical Mfg. Corp.

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Kleer-Plex

PROFESSIONAL FUNGISTAT MAX

1% Clotrimazole Transdermal Liquid

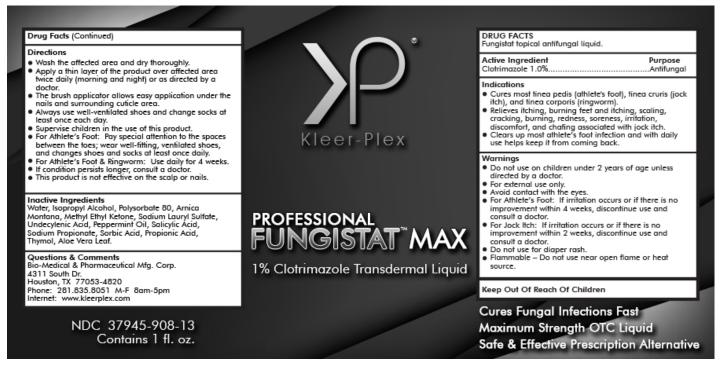
NDC 37945-908-13

Contains 1 fl. oz.

Cures Fungal Infections Fast

Maximum Strenth OTC Liquid

Safe & Effective Prescription Alternative



FUNGISTAT MAX

clotrimazole transdermal liquid liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37945-908	
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 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ARNICA MONTANA (UNII: O80TY208ZW)	
UNDECYLENIC ACID (UNII: K3D86KJ24N)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM PROPIONATE (UNII: DK6 Y9 P42IN)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBIC ACID (UNII: X045WJ989B)	
PROPIONIC ACID (UNII: JHU490RVYR)	
THYMOL (UNII: 3J50 XA376E)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYL ETHYL KETONE (UNII: 6 PT9 KLV9 IO)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:37945-908-12	1 in 1 BOX	04/12/2016		
1	NDC:37945-908-13	30 mL in 1 BOTTLE; 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	04/12/2016		

Labeler - Bio-Medical & Pharmaceutical Manufacturing Corporation (072186356)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(37945-908)	