

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.

4311 South Dr.

Houston, TX 77053-4820

Phone: 281.835.8051 M-F 8am-5pm

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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 Strength OTC Liquid

Safe & Effective Prescription Alternative

<p>Drug Facts (Continued)</p> <p>Directions</p> <ul style="list-style-type: none"> • 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 change 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. 	 <p>Kleer-Plex</p> <p>PROFESSIONAL FUNGISTAT MAX</p> <p>1% Clotrimazole Transdermal Liquid</p>	<p>DRUG FACTS Fungistat topical antifungal liquid.</p> <table border="1"> <thead> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Clotrimazole 1.0%</td> <td>Antifungal</td> </tr> </tbody> </table> <p>Indications</p> <ul style="list-style-type: none"> • 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. <p>Warnings</p> <ul style="list-style-type: none"> • 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. 	Active Ingredient	Purpose	Clotrimazole 1.0%	Antifungal
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Contains 1 fl. oz.

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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: DK6Y9P42IN)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBIC ACID (UNII: X045WJ989B)	
PROPIONIC ACID (UNII: JHU490RVYR)	
THYMOL (UNII: 3J50XA376E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYL ETHYL KETONE (UNII: 6PT9KLV9IO)	

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)