

FUNGISTAT MAX- clotrimazole 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 spray.

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.
- Spray a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor.
- Allow product to dry before covering.
- 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.
- For Jock Itch: Use daily for 2 weeks.
- For Jock Itch: Some discomfort upon application is normal and should fade as product dries. Do not

cover until dry.

- 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 & Comments

Bio-Medical & Pharmaceutical Manufacturing Corporation

4311 South Dr., Houston, TX 77053-4820

Phone: 281.835.8051 M-F 8am-5pm

Internet: www.kleerplex.com

Professional Fungistat Max

1% Clotrimazole Athlete's Foot Care

Maximum Strength OTC Spray

Cures Most Athlete's Foot, Jock Itch & Ringworm In 2 Weeks

NDC 37945-910-44

Contains 4 fl. oz

Drug Facts (Continued)**Directions**

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**PROFESSIONAL
FUNGISTAT[™] MAX**
1% Clotrimazole Athlete's Foot Cure



**Maximum Strength OTC Spray
Cures Most Athlete's Foot,
Jock Itch & Ringworm
In 2 Weeks**

NDC 37945-910-44
Contains 4 fl. oz.

Daily use of Fungistat has been shown to cure most cases of Athlete's Foot in less than 2 weeks.

DRUG FACTS

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Keep Out Of Reach Of Children

FUNGISTAT MAX

clotrimazole liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37945-910
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SODIUM PROPIONATE (UNII: DK6Y9P42IN)	

SORBIC ACID (UNII: X045WJ989B)
PROPIONIC ACID (UNII: JHU490RVYR)
WATER (UNII: 059QF0KO0R)
ARNICA MONTANA (UNII: O80TY208ZW)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
SALICYLIC ACID (UNII: O414PZ4LPZ)
THYMOL (UNII: 3J50XA376E)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
METHYL ETHYL KETONE (UNII: 6PT9KLV9IO)
UNDECYLENIC ACID (UNII: K3D86KJ24N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37945-910-45	1 in 1 BOX	04/14/2016	
1	NDC:37945-910-44	118 mL in 1 BOTTLE, SPRAY; 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	04/14/2016	

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

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(37945-910)

Revised: 4/2016

Bio-Medical & Pharmaceutical Manufacturing Corporation