

FORTINIA- clotrimazole cream
The Podiatree Company

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 1%

Purpose

Antifungal

Uses

- cures most athlete's foot infections and ringworm infections
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions

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. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wash affected area and dry thoroughly
- apply a thin layer to the affected area twice daily (morning and night)
- supervise children in the use of this product
- for athlete's foot: pay special attention to spaces between toes; wear well-fitting, ventilated shoes and change socks at least once daily
- for athlete's foot and ringworm, use daily for 4 weeks
- if condition persists longer, consult your doctor
- this product is not effective on the scalp or nails

Other information

Store at controlled room temperature

Questions or Suggestions?

1.855.763.8733 or visit us at www.thepodiatreecompany.com. Our commitment to you is 100% satisfaction. If you are not completely satisfied, please contact us directly for a full refund.

Inactive ingredients

Aloe Barbadosensis Leaf Extract, Butyrospermum Parkii (Shea Butter), Caprylic/Capric Triglyceride, Cetyl Alcohol, Dimethicone, Fragrance, Glycerin, L-Arginine, Olea Europaea (Olive) Fruit Oil, Panthenol, Persia Gratissima (Avocado) Oil, Petrolatum, Simmondsia Chinensis (Jojoba) Esters, Stearic Acid, Stearyl Alcohol, Sodium Hydroxymethylglycinate, Titanium Dioxide, Triethanolamine, Urea (20%), Water

PRINCIPAL DISPLAY PANEL



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Manufactured for: The Podiatree Company Hailbrook, NY 11741 Made in U.S.A.	
639314800616	

FORTINIA

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54633-314
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
METHYL L-ARGININE (UNII: W6957UBY9Z)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PANTHENOL (UNII: WV9CM0067Z)	
PETROLATUM (UNII: 4T6H12BN9U)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TROLAMINE (UNII: 9O3K93S3TK)	
UREA (UNII: 8W8T17847W)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
SODIUM HYDROXYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHICONE 1000 (UNII: MCU2324216)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLIC/CAPRIC/LINOLEIC TRIGLYCERIDE (UNII: U73D397055)	
WATER (UNII: 059QF0K00R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54633-314-80	80 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/02/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	02/02/2015	

Labeler - The Podiatree Company (078656000)**Establishment**

Name	Address	ID/FEI	Business Operations
EMS Contract Packaging		048602791	manufacture(54633-314)

