

FORTINIA OF- clotrimazole 1% solution

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.

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

Flammable

Do not use near heat or flame, or while smoking. Cap tightly and store at room temperature away from heat.

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 or pharmacist if

- irritation occurs
- there is no improvement within 4 weeks

KEEP OUT OF REACH OF CHILDREN.

In case of accidental ingestion, seek medical help or contact a Poison Control Center immediately.

Directions

- wash affected area and dry thoroughly

- apply one drop to the affected area twice daily (morning and night) or as directed by your doctor
- using a disposable cotton swab, spread a thin layer over the affected area
- discard cotton swab
- 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 shoes and socks at least once daily
- for athlete's foot and ringworm infections, use daily for 4 weeks
- this product is not effective on scalp or nails

Other Information

Store at controlled room temperature.

Inactive Ingredients

Ethyl Alcohol (79%), Propylene Glycol

Questions or Suggestions?

1.855.763.8733 or visit us at www.thepodiatreecompany.com

PRINCIPAL DISPLAY PANEL



FORTINIA OF

clotrimazole 1% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54633-017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54633-017-01	29.57 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	07/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	07/05/2017	

Labeler - The Podiatree Company (078656000)

Revised: 12/2017

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