FORTINIA- 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

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

Aloe barbadensis leaf extract, lavandula augustifolia (lavender) oil, olea europaea (olive) leaf extract, PEG 400, polysorbate 80, SD alcohol (9.75%), tocopheryl acetate (Vitamin E), tritium vulgare (wheat) germ oil

Questions or Suggestions?

1.855.763.8733 or visit us at www.thepodiatreecompany.com

PRINCIPAL DISPLAY PANEL

Label

FORTINIA
clotrimazole 1% solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54633-214
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**
ALOE (UNII: V5VD430YW9)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALCOHOL (UNII: 3K9958V90M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WHEAT GERM OIL (UNII: 14C97E680P)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54633-214-01	29.57 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	10/01/2014	

Labeler - The Podiatree Company (078656000)

Revised: 12/2017 The Podiatree Company