

FORTICEPT ANTIFUNGAL COOLING- clotrimazole liquid

Cosco International, Inc.

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/Purpose

Clotrimazole USP 1%.....Antifungal

Uses

- cures most athlete's foot infections (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis) 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.

Stop use and ask a doctor if irritation occurs or there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch).

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
- Spray a thin layer over 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 the toes, wear well-fitting, ventilated shoes and change socks at least once daily
- For athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition persists longer, ask a doctor. This product is not effective on the scalp or nails

Other Information store between 20° - 25°C (68° - 77°F)

ⓘ Inactive ingredients:

Aquaxyl, Dicaprylyl Carbonate, Dimethicone, Eucalyptus Oil, Glycerin, Lavender Oil, Montanov L, Oat Milk, Polyhexanide, Sepimax Zen, Simulgel INS100, Sodium Phytate, Sunflower Oil, Tea Tree Oil, Water

60g



ANTIFUNGAL COOLING SPRAY

MAXIMUM STRENGTH

(Clotrimazole 1%)

Menthol

+

Tea Tree & Eucalyptus

*Relieves itching, burning,
cracking, and scaling*

For the treatment of most:

**Athlete's Foot
Jock Itch
Ringworm**

NET WT 2oz./60g

LIDAN, INC 30 WALL STR. 8th FLOOR NEW YORK, NY 10005 USA WWW.FORTICEPT.COM

FORTICEPT™ ANTIFUNGAL COOLING SPRAY

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For questions, please call:

+1 212 709-8133

MADE IN USA



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PATENT PENDING

120g



FORTICEPT™
ANTIFUNGAL COOLING SPRAY

MAXIMUM STRENGTH

(Clotrimazole 1%)

Menthol

+

Tea Tree & Eucalyptus

*Relieves itching, burning,
cracking, and scaling*

For the treatment of most:

**Athlete's Foot
Jock Itch
Ringworm**

NET WT 4oz./120g

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PATENT PENDING

FORTICEPT ANTIFUNGAL COOLING

clotrimazole liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52261-0502
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	858.5 g in 1000 g
glycerin (UNII: PDC6A3C0OX)	20 g in 1000 g
dimethicone (UNII: 92RU3N3Y1O)	20 g in 1000 g

oat (UNII: Z6J799EAJK)	15 g in 1000 g
C14-22 Alcohols (UNII: B1K89384RJ)	15 g in 1000 g
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	10 g in 1000 g
sunflower oil (UNII: 3W1JG795YI)	10 g in 1000 g
polydextrose (UNII: VH2XOU12IE)	10 g in 1000 g
polihexanide hydrochloride (UNII: 4XI6112496)	10 g in 1000 g
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.s at 1%) (UNII: 86FQE96TZ4)	3.4 g in 1000 g
isohexadecane (UNII: 918X1OUF1E)	3.3 g in 1000 g
polysorbate 60 (UNII: CAL22UVI4M)	3.3 g in 1000 g
lavender oil (UNII: ZBP1YXW0H8)	3 g in 1000 g
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	3 g in 1000 g
PHYTATE SODIUM (UNII: 88496G1ERL)	2 g in 1000 g
eucalyptus oil (UNII: 2R04ONI662)	2 g in 1000 g
Tea Tree oil (UNII: VIF565UC2G)	1.5 g in 1000 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-0502-0	60 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/04/2016	
2	NDC:52261-0502-1	120 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/04/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/04/2016	

Labeler - Cosco International, Inc. (016433141)

Registrant - Cosco International, Inc. (016433141)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(52261-0502) , label(52261-0502) , pack(52261-0502)

Revised: 5/2016

Cosco International, Inc.