

FORTICEPT ANTIFUNGAL BALM- tolmaftate 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

Tolnaftate 1% w/w.....Antifungal

Uses

Proven clinically effective in the treatment and prevention of most athlete's foot (tinea pedis), ringworm (tinea corporis), and jock itch (tinea cruris).

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

- Read all package directions and warnings before use. Use only as directed.
- Clean the affected area with soap and warm water and dry thoroughly.
- Apply a thin layer of FORTICEPT™ COOLING BALM over the affected area twice daily (morning and night), or as directed by a doctor.
- 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, use daily for 4 weeks. If condition persists longer, consult a doctor.
- Intended for use by normally healthy individuals only.
- Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor.
- Supervise children in the use of this product.

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

❏ **Inactive ingredients:**

Acticire®, Capric Caprylic Triglyceride, Dimethicone, Eucalyptus Oil, Glyceryl Behenate, Glyceryl Stearate, Lavender Oil, LexFeel® N5, Methyl Lactate, PEG 40 Hydrogenated Castor Oil, Polyhexanide, Sunflower Oil, Tea Tree Oil, Water

30g



FORTICEPT™
ANTIFUNGAL COOLING BALM

MAXIMUM STRENGTH

(TOLNAFTATE 1%)

**Menthol
Tea Tree & Eucalyptus**

- Overnight Formula
- Helps Cure and Prevent Fungal Infections
- Protective Barrier Stays on All Night

Relieves itching & burning

Cures and prevents most:

**Athlete's Foot
Ringworm
Jock Itch**

NET WT 1oz./30g

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

FORTICEPT™ ANTIFUNGAL COOLING BALM

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For questions, please call:
+1 212 709-8133

MADE IN USA



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PATENT PENDING

60g



FORTICEPT™
ANTIFUNGAL COOLING BALM

MAXIMUM STRENGTH
 (TOLNAFTATE 1%)

Menthol
Tea Tree & Eucalyptus

- Overnight Formula
- Helps Cure and Prevent Fungal Infections
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Relieves itching & burning

Cures and prevents most:

Athlete's Foot
Ringworm
Jock Itch

NET WT 2oz./60g

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FORTICEPT ANTIFUNGAL BALM

tolnaftate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:5226 1-0 100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
tolnaftate (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	tolnaftate	10 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	415.7 g in 1000 g
sunflower oil (UNII: 3W1JG795YI)	158.225 g in 1000 g
dimethicone (UNII: 92RU3N3Y1O)	150 g in 1000 g
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)	80 g in 1000 g

glyceryl monostearate (UNII: 230OU9XXE4)	65 g in 1000 g
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	50 g in 1000 g
peg-40 castor oil (UNII: 4ERD2076EF)	25 g in 1000 g
polyglyceryl-10 oleate (UNII: 55C81W76DH)	24.675 g in 1000 g
POLIHEXANIDE HYDRO CHLORIDE (UNII: 4XI6112496)	10 g in 1000 g
methyl lactate, (-) (UNII: 0379G9C44S)	4 g in 1000 g
tea tree oil (UNII: VIF565UC2G)	2.5 g in 1000 g
eucalyptus oil (UNII: 2R04ONI662)	1.8 g in 1000 g
GLYCERYL CAPRATE (UNII: 197M6VFC1W)	1.05 g in 1000 g
ACACIA DECURRENS FLOWER (UNII: 8PHF3LSM61)	1.05 g in 1000 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-0100-0	30 g in 1 TUBE; Type 0: Not a Combination Product	05/04/2016	
2	NDC:52261-0100-1	60 g in 1 TUBE; 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(52261-0100) , label(52261-0100) , pack(52261-0100)

Revised: 5/2016

Cosco International, Inc.