

TOLFYRA- tolnaftate liquid
Oncora Pharma, LLC

Tolfyra™

Tolnaftate 1% Antifungal Liquid

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- for the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis).
- relieves itching, burning, cracking, scaling, and discomfort which accompany these conditions.
- for the prevention of most Athlete's foot with daily use.
- eliminates fungus on fingers, toes, and around the nails.
- eliminates and helps stop the spread of fungal infections on cuticles around nail edges and under the nail tips where reachable with applicator brush.

Warnings

For external use only

Do not use on

children under 2 years of age unless directed by a doctor.

When using this product

- do not get into eyes

Stop use and ask a doctor

- for athlete's foot and ringworm - if irritation occurs or there is no improvement within 4 weeks
- for prevention of athlete's foot - if irritation occurs, discontinue use and consult a doctor

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean the affected area and dry thoroughly
- apply a thin layer of the product over affected area twice daily (morning and night) paying special attention to the edges of the nail, cuticles, and skin around the nails or as directed by a doctor
- 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 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.

Use under the direction of a medical practitioner

Other information

- Store at 15 - 30°C (59° - 86°F) [see USP Controlled Room Temperature].
- avoid excessive heat
- do not use if package is damaged

How Supplied

Tolfyra™ Tolnaftate 1% Antifungal Solution is supplied in a 1 fl oz / 30 mL glass bottle with a screw cap fitted with a brush (NDC 85477-331-01)

Inactive ingredients

The inactive ingredients in Tolfyra™ (tolnaftate 1% solution) are purified water, PEG-8, cetearyl alcohol, ceteth-20 phosphate, decetyl phosphate, propylene glycol, cocamidopropyl betaine, polysorbate 20, glyceryl stearate, stearyl alcohol, hydroxyethyl cellulose, imidazolidinyl urea, cetyl alcohol, methylparaben, propylparaben, triethanolamine, and citric acid.

Tolfyra™

Manufactured in the USA by:

Oncora Pharma LLC

Dallas TX 75228

For questions or information
call toll-free: **833-242-4493**

85477-331-01



FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

1 oz (30ml)

Directions

• Clean or wash the affected area and dry thoroughly. Apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor. 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, use daily for 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor. For toenail fungus, apply to skin around the nail and cuticle.

Storage: Store at 15° to 30°C (59° to 86°F). [see USP Controlled Room Temperature]. Avoid excessive heat.

Distributed by:
Oncora Pharma
Dallas, TX 75228
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Drug Facts

Active Ingredients	Purpose
Tolnaftate 1%	Antifungal

Uses • Effective treatment of athlete's foot, jock itch and ringworm.

Warnings

- For external use only.
- Avoid contact with the eyes.
- Do not use on children under 2 years of age unless directed by a doctor.
- Keep this and all drugs out of the reach of children.
- If treating athlete's foot and ringworm: If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor.
- If treating jock itch: If irritation occurs or if there is no improvement within 2 weeks, discontinue use and consult a doctor.
- If swallowed, get medical help or contact a Poison Control Center right away.

Inactive Ingredients

Purified water, PEG-8, Cetearyl alcohol and Ceteth-20 phosphate and dicetyl phosphate, Propylene glycol, Cocamidopropyl betaine, Polysorbate 20, Glyceryl stearate, Stearyl alcohol, Hydroxyethyl cellulose, Imidazolidinyl urea, Cetyl alcohol, Methylparaben, Propylparaben, Triethanolamine, Citric acid

pdp

TOLFYRA

tolnaftate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85477-331
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	0.3 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PEG-8 (UNII: B697894SGQ)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
DICETYL PHOSPHATE (UNII: 2V6E5WN99N)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
IMIDAZOLIDINYL UREA (UNII: M629807ATL)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

TRIETHANOLAMINE (UNII: 9O3K93S3TK)

CITRIC ACID ACETATE (UNII: DSO12WL7AU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85477-331-01	30 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/01/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	05/01/2026	

Labeler - Oncora Pharma, LLC (119482542)

Revised: 5/2026

Oncora Pharma, LLC