

**TOLCYLEN ANTIFUNGAL SOLUTION- tolnaftate solution**  
**Marlinz Pharma, LLC**

*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.*

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**Active Ingredient**

Tolnaftate 1%

**Purpose**

Antifungal

**Warnings**

Keep out of reach of children

**Uses**

Cures most Athlete's Foot (Tinea Pedis) ■ Relieves itching, cracking, burning and scaling, which accompanies this condition ■  
Prevents recurrence of Athlete's Foot

**Warnings**

Do not use on children under 2 years of age ■ For external use only ■ Avoid contact with the eyes. If eye contact occurs, wash thoroughly with water ■ Stop use and consult a physician if irritation occurs or if there is no improvement within four (4) weeks ■ Keep out of reach of children ■ If swallowed, get medical help or contact a poison control center right away ■ If pregnant or breast-feeding, ask a health-care professional before use.

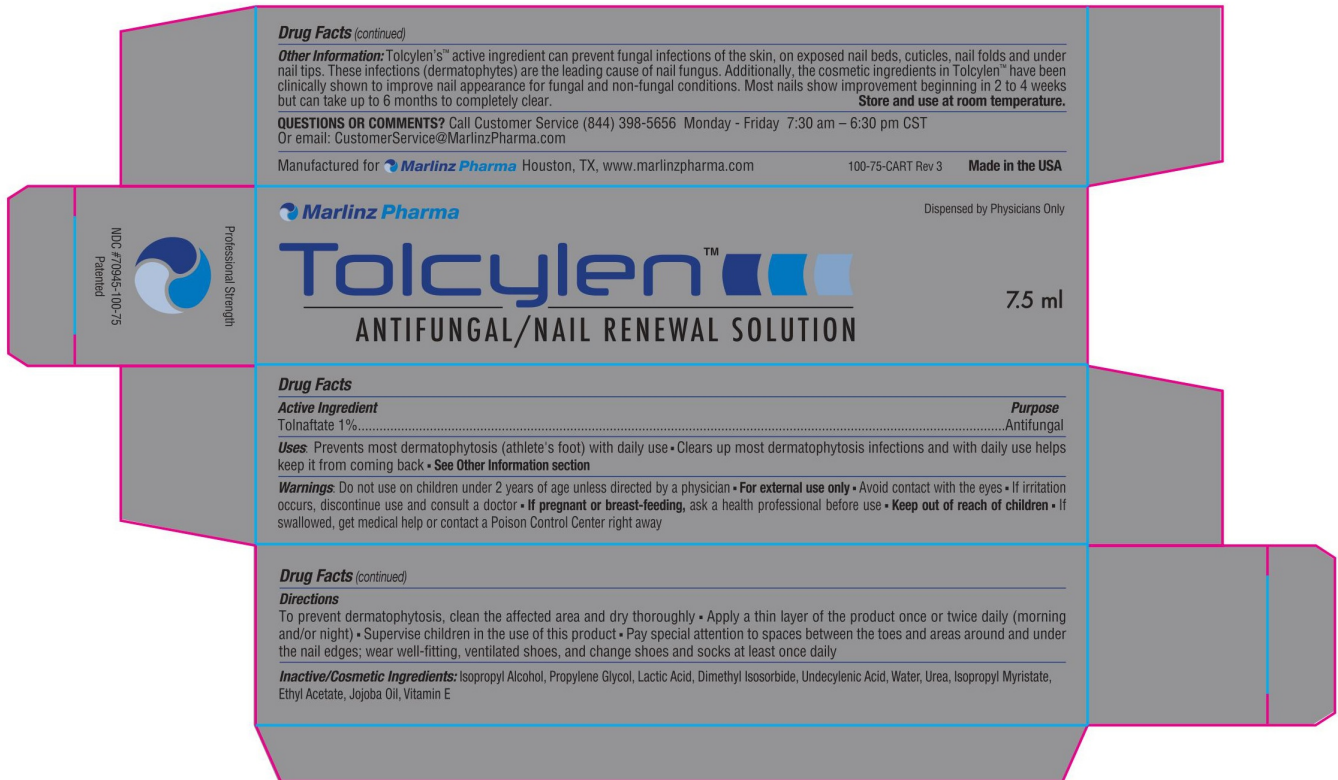
**Directions**

Wash the affected area with soap and water.  
■ Dry thoroughly, then apply a thin layer over the affected area.  
■ Use twice daily (morning and night) or as directed by a physician.  
■ Pay special attention to the spaces between the toes and the areas around the edges and under the front of the nails.  
■ Wear well-fitted ventilated shoes and change socks at least once daily.  
■ Use daily for four (4) weeks. If condition persists longer, consult a physician.  
■ Wash hands after each use. Store and use at room temperature.

## Inactive Ingredieints

Inactive Ingredients: Ethyl Acetate, Isopropyl Alcohol, Isopropyl Myristate, Propylene Glycol, Water

Cosmetic Ingredients: Urea, Lactic Acid, Jojoba Oil, Undecylenic Acid, Dimethyl Isosorbide, Vitamin E



## TOLCYLEN ANTIFUNGAL SOLUTION

tolnaftate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70945-100
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 mg in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>LACTIC ACID</b> (UNII: 33X04XA5AT)	
<b>ETHYL ACETATE</b> (UNII: 76845O8NMZ)	
<b>UREA</b> (UNII: 8W8T17847W)	
<b>UNDECYLENIC ACID</b> (UNII: K3D86KJ24N)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	

### Product Characteristics

<b>Color</b>	yellow (Clear Fluid)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70945-100-75	1 in 1 CARTON	12/16/2016	
1		7.5 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/16/2016	

**Labeler** - Marlinz Pharma, LLC (080251509)

Revised: 2/2022

Marlinz Pharma, LLC