

**FUNGIFREE NAIL FUNGUS TREATMENT- ketoconazole, tolnaftate solution  
YITONGBADA (SHENZHEN) INTERNATIONAL TRADE CO., LTD**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Ketoconazole 1.7%.....	Anti-fungal
Tolnaftate 1.0%.....	Anti-fungal
<b>Uses</b>	
- Treatment of fingernail and toenail fungus	
<b>Warnings</b>	
<b>For external use only</b>	
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Do not use on children under 2 years of age unless directed by a doctor.	
When using this product avoid contact with eyes.	
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Stop and ask a doctor if - irritation occurs - there is no improvement within 6 weeks	
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If pregnant or breast-feeding, ask a health professional before use.	
Keep out of reach of children. In case of accidental ingestion, seek medical advice immediately or contact a Poison Control Center right away.	
<b>Directions</b>	
-Soak your nails in warm water for 5 minutes, then dry them.	
-Cut and trim affected nails.	
-Dip the brush (attached on cap) into the treatment solution.	
-Apply the solution over the affected parts, including the root(s) of the nail(s).	
-Use 2 times a day, in the morning and before sleep.	
<b>Other information</b> store at 10-35°C (50.0-95.0°F)	
<b>Inactive ingredients</b> Aqua, Sorbitol, Ethanol, Propylene Glycol, Salicylic Acid, Deacetylated Chitin, Angelica Dahurica, Lactic Acid, Chlorhexidine Acetate, Laurocapram	
<b>Questions or comments?</b> Contact us at <a href="mailto:support@fungifree.com">support@fungifree.com</a>	

Active ingredients Purpose

Ketoconazole  
1.7%.....Anti-fungal

Tolnaftate  
1.0%.....Anti-fungal

## Treatment of fingernail and toenail fungus

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## FUNGIFREE NAIL FUNGUS TREATMENT

ketoconazole, tolnaftate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83364-005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>KETOCONAZOLE</b> (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZOLE	1.7 g in 100 g
<b>TOLNAFTATE</b> (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>LACTIC ACID</b> (UNII: 33X04XA5AT)	
<b>CHLORHEXIDINE ACETATE</b> (UNII: 5908ZUF22Y)	
<b>LAUROCAPRAM</b> (UNII: 1F3X9DRV9X)	

<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANGELICA DAHURICA VAR. FORMOSANA WHOLE</b> (UNII: 247A107296)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLIGLUSAM</b> (UNII: 82LKS4QV2Y)	
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83364-005-01	1 in 1 BOX	05/16/2024	
1	NDC:83364-005-02	30 g in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/16/2024	

**Labeler** - YITONGBADA (SHENZHEN) INTERNATIONAL TRADE CO., LTD (725220463)

Revised: 5/2024

YITONGBADA (SHENZHEN) INTERNATIONAL TRADE CO., LTD