

FUNGAL NAIL PATCHES- tolnaftate patch
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.

Drug Facts

Drug Facts	
Active ingredients	Purpose
Tolnaftate 1.0%.....	Anti-fungal
Uses	
- Repairs fungal nail damage and improves nail appearance	
Warnings	
For external use only	

Do not use on children under 3 years of age unless directed by a doctor.	
When using this product avoid contact with eyes. In case of contact, rinse thoroughly with water	

Stop and ask a doctor if - irritation occurs - there is no improvement within 4 weeks	

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	
Directions	
- Remove any nail polish before use. Clean and thoroughly dry the affected area. - Peel off the protective film from the patch, starting with the outer edge and then the inner side. - Center the white area of the patch over the infected part of the nail. - Apply the adhesive side directly onto the nail. - Wrap the sides of the patch around the toe or finger to ensure a snug fit. - Fold the remaining adhesive part over the toe or fingertip. - Leave the patch on for 6-8 hours. For best results, use overnight for 3-6 months	
Other information Store at room temperature 15°-30°C (59°-86°F), away from excess heat and direct sun	
Inactive ingredients Glycerin, Tartaric Acid, Polysorbate 80, 1,2-Hexanediol, Disodium EDTA, Cellulose Gum, Sodium Polyacrylate, Aluminum Glycinate, Fumaric Acid, Butylene Glycol, Urea, Water	
Questions or comments? Contact us at support@fungifree.com	

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FUNGAL NAIL PATCHES

tolnaftate patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83364-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FUMARIC ACID (UNII: 88XHZ13131)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
TARTARIC ACID (UNII: W4888I119H)	

GLYCERIN (UNII: PDC6A3C0OX)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)
UREA (UNII: 8W8T17847W)
EDETATE DISODIUM (UNII: 7FLD91C86K)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83364-011-01	21 in 1 BOX	09/24/2024	
1		0.7 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/24/2024	

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

Revised: 8/2024

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