

**FUNGAL NAIL TREATMENT- fungal nail treatment liquid**  
**Gaoye Marketing Inc**

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**85308-002**

**Active Ingredient**

Undecylenic Acid 25%

**Purpose**

Antifungal

**Use**

For the effective treatment of nail fungus, discoloration, thickening, splitting, crumbling and brittleness.

**Warnings**

For external use only.

Do not use

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

Stop use and ask a doctor

- if irritation occurs or if there is no improvement within 4 weeks.

When using this product

- Possible

side effects may include mild skin irritation, redness, or itching at the application site.

Discontinue use and consult a doctor if severe reactions (e.g., swelling, rash) occur.

Keep out of reach of children.

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

**Do not use**

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

**When Using**

When using this product

- Possible

side effects may include mild skin irritation, redness, or itching at the application site.

Discontinue use and consult a doctor if severe reactions (e.g., swelling, rash) occur.

**Stop Use**

Stop use and ask a doctor

●if irritation occurs or if there is no improvement within 4 weeks.

### **Ask Doctor**

Stop use and ask a doctor

●if irritation occurs or if there is no improvement within 4 weeks.

### **Keep Out Of Reach Of Children**

Keep out of reach of children.

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

### **Directions**

Directions

1. Apply the product twice a day, in the morning and at night.
2. For initial use, soak the affected nail in warm water to soften it. Gently file the nail to make it thinner and remove dirt, being cautious not to harm the nail bed. For best results file nails every 2-3 days.
3. Hold the bottle at an angle to pour 2-3 drops. Use the brush applicator to apply the solution on the affected areas.
4. For best results, use this product consistently for 3-6 months, as fungal nail infections require prolonged treatment. Visible improvements may appear in as little as 7 days, but complete healing takes longer.

### **Other information**

Preservation method

Store in a cool, shaded place away from direct sunlight. Store at room temperature between 15-30°C (59-86°F).

### **Inactive ingredients**

Inactive ingredients

Aloe Vera Extract, Canola Oil, Clove Bud Oil, Lavender Oil, Jojoba Oil, Manuka Oil, Oregano Oil, Peppermint Oil, Propolis Extract, Sweet Almond Oil, Tea Tree Oil, Tocopheryl Acetate.

### **Questions**

Syuekisei@hotmail.com

### **PRINCIPAL DISPLAY PANEL**



## FUNGAL NAIL TREATMENT

fungal nail treatment liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85308-002
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	25 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
CANOLA OIL (UNII: 331KBJ17RK)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CLOVE OIL (UNII: 578389D6D0)	
JOJOBA OIL (UNII: 724GKU717M)	
MANUKA OIL (UNII: M6QU9ZUH2X)	

<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>OREGANO LEAF OIL</b> (UNII: 7D0CGR40U1)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85308-002-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	04/03/2025	

**Labeler -** Gaoye Marketing Inc (119447516)

### Establishment

Name	Address	ID/FEI	Business Operations
Gaoye Marketing Inc		119447516	manufacture(85308-002)

Revised: 4/2025

Gaoye Marketing Inc