

**SYLVIRENE FUNGAL NAIL RENEWAL- tolnaftate 1% fungal nail renewal liquid**  
**Jiangxi Hemei Pharmaceutical Co., Ltd**

-----

**84010-073**

**Active Ingredient**

Tolnaftate 1%

**Purpose**

Antifungal

**Use**

Cures most Athlete's Foot (Tinea Pedis) and Ringworm (Tinea Corporis). Relieves itching, scaling, cracking, burning, redness, sorenes, and irritation and discomfort.

Helps prevent most athlete'sfoot (dermatophytosis) with daily use.

**Warnings**

For external use only.

**Do not use**

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

**When Using**

avoid contact with eyes.

**Stop Use**

irritation occurs, there is no improvement within 4 weeks (for athlete's foot and ringworm).

**Ask Doctor**

irritation occurs, there is no improvement within 4 weeks (for athlete's foot and ringworm).

**Keep Oot Of Reach Of Children**

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

### **Directions**

For athlete's foot and ring worm: use daily for 4 weeks. Clean the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. This product

is not effective for the treatment of ring worm of the scalp or nails. 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. To prevent athlete's foot, apply once or twice daily (morning and/or night). Apply to skin around the nail and cuticle.

### **Other information**

Store at room temperature 15-30°C (59-86°F)

### **Inactive ingredients**

water, euphorbia hirta whole, glycerin, hydroacrylic acid, pseudolarix amabilis bark, resorcinol.

### **PRINCIPAL DISPLAY PANEL**

**SYLVIRENE**<sup>TM</sup>

**Drug Facts**

**Active ingredient.....Purpose**  
Tolnaftate 1%.....Antifungal

**Uses**

Cures most Athlete's Foot (Tinea Pedis) and Ringworm (Tinea Corporis). Relieves itching, scaling, cracking, burning, redness, sores, and irritation and discomfort. Helps prevent most athlete's foot (dermatophytosis) with daily use.

**Warnings** For external use only.

**Do not use** on children under 2 years of age unless directed by a doctor.

**When using this product,** avoid contact with eyes.

**Stop use and ask a doctor if** irritation occurs, there is no improvement within 4 weeks (for athlete's foot and ringworm).

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** For athlete's foot and ring worm: use daily for 4 weeks. Clean the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily (morning and night) or

**SYLVIRENE**<sup>TM</sup>

**MAXIMUM STRENGTH**

**FUNGAL NAIL RENEWAL**

- ◆ Reduce Fungus
- ◆ Restore and Renews
- ◆ Protects from Reinfection



MEDICAL STRENGTH  
NET WT: 30ml / 1fl oz

as directed by a doctor. Supervise children in the use of this product. This product is not effective for the treatment of ring worm of the scalp or nails. 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. To prevent athlete's foot, apply once or twice daily (morning and/or night). Apply to skin around the nail and cuticle.

**Other information** Store at room temperature 15-30 C (59-86°F)

**Inactive ingredients** water, euphorbia hirta whole, glycerin, hydroxylic acid, pseudolarix amabilis bark, resorcinol.



NINTH FLOOR, UNIT 1, BUILDING 1,  
ORIENTAL PEARL, ZHANGSHU, JIANGXI  
331200, CHINA (CHN).  
MANUFACTURED BY:JIANGXI HEMEI  
PHARMACEUTICAL CO., LTD.



**SYLVIRENE**<sup>TM</sup>

**MAXIMUM STRENGTH**

**FUNGAL NAIL RENEWAL**

- ◆ Reduce Fungus
- ◆ Restore and Renews
- ◆ Protects from Reinfection



MEDICAL STRENGTH  
NET WT: 30ml / 1fl oz

**SYLVIRENE FUNGAL NAIL RENEWAL**

tolnaftate 1% fungal nail renewal liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84010-073
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

## Inactive Ingredients

Ingredient Name	Strength
<b>RESORCINOL</b> (UNII: YUL4LO94HK)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PSEUDOLARIX AMABILIS BARK</b> (UNII: 49G13A93VE)	
<b>EUPHORBIA HIRTA WHOLE</b> (UNII: L13YF113GN)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDRACRYLIC ACID</b> (UNII: C4ZF6XLD2X)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84010-073-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/18/2025	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	02/18/2025	

**Labeler** - Jiangxi Hemei Pharmaceutical Co., Ltd (724892056)

## Establishment

Name	Address	ID/FEI	Business Operations
Jiangxi Hemei Pharmaceutical Co., Ltd		724892056	manufacture(84010-073)

Revised: 2/2025

Jiangxi Hemei Pharmaceutical Co., Ltd