# FUNGICURE LIQUID GEL- clotrimazole gel Alva-Amco Pharmacal Companies, Inc.

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### **Fungicure Liquid Gel**

### **Active Ingredient**

Clotrimazole 1% w/w

### **Purpose**

**Antifungal** 

#### Uses

For the cure of most

- ringworm (tinea corporis)
- athlete's foot (tinea pedis)

For relief of

- itching
- scaling
- cracking
- burning
- redness
- soreness
- irritation
- discomforts which may accompany these conditions.

### **Warnings**

For external use only

**Ask a doctor before use** on children under 2 years of age.

When using this product avoid contact with eyes.

### Stop use and ask a doctor if

- Irritation occurs
- There is no improvement within 4 weeks.

**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

#### **Directions**

- Read all package directions and warnings before use.
- Use only as directed.
- Clean the affected area with soap and warm water and dry thoroughly.
- Apply a thin layer of Fungicure over the affected area twice daily (morning and night), or as directed by a doctor.
- This product is not effective on scalp or nails.
- Avoid applying to severely cracked or irritated areas.
- For ringworm and athlete's foot, use daily for 4 weeks. If condition persists longer, consult a doctor.
- For athlete's foot, pay special attention to spaces between toes; wear well fitting, ventilated shoes, and change shoes and socks at least once daily.
- Intended for use by normally healthy adults only.
- Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor.
- Supervise children in the use of this product.

#### Other information

- Fungicure may be applied to exposed nail-beds, cuticles, around nail edges and under nail tips where reachable with its applicator brush.
- This product is not intended to, nor will it, penetrate hard nail surfaces.
- While not all finger and toe fungal infections are curable with OTC topical medications, if you see improvement within 4 weeks of use, you may continue to use Fungicure until satisfactory results are obtained.
- You may report serious side effects to the phone number provided under *Questions?* below.

### **Inactive ingredients**

Hydroxypropylcellulose and isopropyl alcohol.

Questions? 1-800-792-2582

# Fungicure Maximum Strength Liquid Gel Insert

### Maximum Strength FUNGICURE Liquid Gel

### **Anti-Fungal Treatment**

Kills 6 types of fungus on fingers and toes including around nails where reachable with its Quickbrush applicator.

#### WHAT IS FUNGUS INFECTION OF THE FINGER AND TOE AREAS?

Common fungus infections of the fingers and toes are caused by a variety of fungi; actual living organisms (members of the yeast and mold family) which thrive in dark, moist conditions. Using small breaches in the skin's surface, these organisms can cause infection by contact with infected surfaces, animals or people. Once infection starts,

spreading may occur. For example, infected fingers and toes may infect other fingers and toes. Although such infections often develop slowly, they may be difficult to eliminate if not treated promptly with an effective anti-fungal medicine like **Fungicure**.

#### HOW DO YOU KNOW IF YOU HAVE A TOPICAL FUNGUS INFECTION?

Some topical fungal infections may present themselves on the skin as ring-like formations with clear centers; this is commonly called ringworm. Athlete's foot fungus, when in the finger and toe areas, is often characterized by scaling of skin, burning, cracking, itching, and related discomforts. When nails become infected, they may appear to become opaque (cloudy white), thickened, brittle, easily broken, and in some cases, discolored (greenish/brown).

#### **UNDERSTANDING AND TREATING A NAIL AREA INFECTION:**

Fungal infections of the nail areas are often caused by the same fungi that lead to athlete's foot and ringworm infections elsewhere on the body. These fungi can infect the entire area around the nails including the cuticles, the nail beds, and even the nails themselves. When infected finger/toe nails are intact, over-the-counter topical antifungal treatments may not be able to penetrate and kill the fungus; this is why all OTC topical treatments must indicate they are not effective on the nails. However, in instances of advanced infection, the nails often are not intact; they may be missing, cracked open, or lifted away, exposing the infected nail bed. In these instances **FUNGICURE Anti-Fungal Liquid Gel**, with its powerful anti-fungal formula, can reach and kill nail bed fungus by direct application or related capillary action. **Fungicure** cures the infection, allowing the natural regrowth of healthy looking tissue.

NOTE: Fungal infections which are isolated beneath an intact nail or embedded within the nail itself may require consultation from a doctor for proper treatment.

#### **HOW FUNGICURE LIQUID GEL WORKS:**

MAXIMUM STRENGTH **FUNGICURE Liquid Gel** contains Clotrimazole, a widely recognized anti-fungal ingredient that has been proven to be effective against 6 types of fungus such as E. floccosum, T. mentagrophytes, M. canis, M. gypseum, T. tonsurans and T. rubrum.

When applied as directed, **FUNGICURE Liquid Gel** acts promptly to target, destroy, and prevent the spread of infection by inhibiting the growth and reproduction of fungal cells.

#### PROMPT ACTION AND PROPER TREATMENT:

Early treatment of fungal infections is important. If you suspect that you may have a fungal infection, consult your doctor promptly for advice and proper diagnosis. You may wish to show him/her **FUNGICURE Liquid Gel** and discuss its use. For best results, once treatment is started with **FUNGICURE Liquid Gel**, it is important to carefully follow the treatment instructions on the package until satisfactory results are achieved or advised further by a doctor.

NOTE: Noticeable improvement may be expected within 4 weeks in the case of most ringworm and athlete's foot fungus. Consult your doctor for advice if noticeable improvement is not evident by this time or if condition persists or worsens.

**ACTIVE INGREDIENT:** Clotrimazole 1% w/w

**Uses:** For the cure of most: ringworm (tinea corporis) and athlete's foot (tinea pedis). For relief of: itching, scaling, cracking, burning, redness, soreness, irritation and discomforts which may accompany these conditions.

#### **Warnings:**

For external use only.

**Ask a doctor before use** on children under 2 years of age.

When using this product avoid contact with the eyes.

**Stop use and ask a doctor if** irritation occurs or there is no improvement within 4 weeks.

**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

**Directions:** Read all package directions and warnings before use. Use only as directed. Clean the affected area with soap and warm water and dry thoroughly. Apply a thin layer of **FUNGICURE Liquid Gel** over the affected area (including the exposed nail bed) twice daily (morning and night), or as directed by a doctor. **This product is not effective on scalp or nails.** Avoid applying to severely cracked or irritated areas. For athlete's foot, pay special attention to spaces between toes; wear well fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete's foot and ringworm, use daily for 4 weeks. If condition persists longer, consult a doctor. Intended for use by normally healthy adults only. Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor. Supervise children in the use of this product.

**Other Information:** While not all finger and toe fungal infection are curable with OTC topical medications, if you see improvement within 4 weeks of use, you may continue to use **FUNGICURE** until satisfactory results are obtained. You may report serious side effects to the phone number provided under *Questions?* below.

Inactive ingredients Hydroxypropylcellulose and Isopropyl alcohol.

Questions? 1-800-792-2582

#### fungicure.com

The active ingredient in **Fungicure** has been recognized to be safe and effective by an FDA Expert Advisory Panel when used as directed.



# **FUNGICURE LIQUID GEL**

clotrimazole gel

**Drug Facts** 

Active ingredient

Warnings For external use only.

Ask a doctor before use on children under 2 years of age. When using this product avoid contact with eves.

side effects to the phone number provided under Questions? below.

KEEP CONTAINER

TIGHTLY CLOSED WHEN NOT IN USE. STORE AWAY FROM EXCESSIVE

HEAT AND COLD.

Questions? 1-800-792-2582

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52389-733
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		

l	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	<b>1</b> NDC:52389-733-09	1 in 1 BOX	01/04/2016			
	1	9 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M005	12/31/2015		

Labeler - Alva-Amco Pharmacal Companies, Inc. (042074856)

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