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

Fungicure Manicure Pedicure 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 the 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 athlete's foot and ringworm, 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 precision QuickBrush applicator. 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 Manicure & Pedicure Anti-Fungal Treatment Professional Formula Liquid Gel

- Kills ugly fungus for healthy looking fingers & toes
- Odor free & instant dry
- Liquid Gel locks onto site of infection

The Manicure & Pedicure Fungi Specialist

Maintaining the appearance of your manicure and pedicure requires more than

cosmetics. Many manicure procedures can enhance the risk of fungal infection, and certain types of artificial nails can trap moisture and fungi and create a perfect environment for fungus to grow and spread. Cutting cuticles can also create opportunities for fungal infections. When you promptly treat fungal infections on cuticles and nearby skin surfaces, you reduce the risk of the infections spreading.

Fungicure Manicure & Pedicure Liquid Gel is a maximum strength anti-fungal, specifically formulated for those with professionally or home-manicured, pedicured or artificial nails. **Fungicure's** precision QuickBrush applicator allows for easy application on hard to reach infections, including under nail tips.

WHAT IS FUNGUS INFECTION OF THE FINGER AND TOES?

Common topical fungus infections of the finger 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 surface 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 the nail 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 Manicure & Pedicure 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 Manicure & Pedicure Liquid Gel** contains Clotrimazole, a widely recognized anti-fungal ingredient that has been proven to be effective against 6 types of fungi such as E. floccosum, T. mentagrophytes, M. canis, M. gypseum, T. tonsurans and T. rubrum.

When applied as directed, FUNGICURE Manicure & Pedicure 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 Manicure & Pedicure Liquid Gel** and discuss its use. For best results, once treatment is started with **FUNGICURE Manicure & Pedicure 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 (tinea corporis) and athlete's foot (tinea pedis). 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)
- 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 the 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 the 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 precision QuickBrush applicator brush. This product is not intended to, nor will it, penetrate hard nail surfaces.
- While not all finger and toe area 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

www.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.



147-2RC.

Drug Facts

Active ingredient

Purpose Antifungal

Uses For the cure of most: ■ ringworm (tinea corporis) ■ athlete's foot (tinea pedis). For relief of:

itching scaling cracking burning redness resources irritation discomforts which may accompany these conditions

Warnings

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■ 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

Other Information = FUNGICURE may be applied to exposed nail-beds, cuticles, around nail edges and under nail tips where reachable with its precision QuickBrush applicator. 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 ingredient Hydroxypropylcellulose and Isopropyl alcohol.

Questions? 1-800-792-2582



KEEP CONTAINER TIGHTLY CLOSED WHEN NOT IN USE. STORE AWAY FROM EXCESSIVE HEAT AND COLD.

Maximum Strength

FUNGICURE

Manicure & Pedicure Anti-Fungal Treatment

Professional Formula Liauid Gel

- Odor Free
- Instant Dry
- · QuickBrush Applicator

Contains Clotrimazole, recognized by an FDA Expert Advisory Panel to be safe and effective when used as directed.

Maximum Strength

FUNGICURE.

Manicure & Pedicure **Anti-Fungal Treatment**

Kills Ugly Fungus

Nothing Stronger without a Prescription

Professional Formula Liquid Ge

FUNGICURE

Manicure & Pedicure Anti-Fungal Treatment

Professional Formula Liquid Gel

Contains a Broad Spectrum anti-fungal that kills 6 types of fungus on fingers and toes

Inhibits the growth fungal cells on exposed nail-beds, cuticles, under nail tips where precision QuickBrush™ applicator.

www.FUNGICURE.com



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CP-232065 08/2018

® Reg. U.S. Patent and Trademark Office

0.35 FL OZ (10.5 mL)

Maximum Strength

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FUNGICURE MANICURE PEDICURE LIQUID GEL

clotrimazole gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:52389-647

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

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Basis of Strength 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)

Packaging

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	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:52389- 647-09	1 in 1 BOX	07/06/2016	
	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	07/05/2016				

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

Revised: 5/2024 Alva-Amco Pharmacal Companies, Inc.