FUNGICURE INTENSIVE- clotrimazole liquid Alva-Amco Pharmacal Companies, Inc.

Fungicure Intensive

Active ingredient

Clotrimazole 1% w/v

Purpose

Antifungal

Uses

For the cure of most:

- ringworm (tinea corporis)
- athlete's foot (tinea pedis)
- jock itch (tinea cruris)

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 (2 weeks for jock itch)

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.
- Spray 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; for jock itch, use daily for 2 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.
- Supervise children in the use of this product.
- 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.

Other information

Spray FUNGICURE INTENSIVE on exposed nail-beds, on cuticles, around nail edges and under nail tips. 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 INTENSIVE until satisfactory results are obtained. You may report serious side effects to the phone number provided under *Questions?* below.

Inactive ingredient

Isopropyl alcohol

Questions? 1-800-792-2582

Package Insert

Maximum Strength

FUNGICURE INTENSIVE

Anti-Fungal Treatment

Cures Finger and Toe Area Fungal Infections

Kills 6 Types of Fungus on Exposed Nail-Beds

WHAT IS FUNGUS INFECTION OF THE FINGER AND TOES?

Common topical 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 surface as ring-like formations with clear centers; this is commonly called ringworm. Athlete's foot fungus and jock itch fungus, when in the finger and toe areas, are 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, jock itch, 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 not intact; they may be missing, cracked open or lifted away, exposing the infected nail bed. In these instances **FUNGICURE Intensive**, 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 INTENSIVE WORKS:

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

When applied as directed, **FUNGICURE Intensive** 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 Intensive** and discuss its use. For best results, once treatment is started with **FUNGICURE Intensive**, 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), two weeks for most jock itch (tinea cruris). Consult your doctor for advice if noticeable improvement is not eveident by this time or if condition persists or worsens.

Active ingredient: Clotrimazole 1% w/v

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Other Information: Spray FUNGICURE INTENSIVE on exposed nail-beds, on cuticles, around nail edges and under nail tips. 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 INTENSIVE until satisfactory results are obtained. You may report serious side effects to the phone number provided under *Questions?* below.

Inactive ingredient: Isopropyl alcohol

Questions? 1-800-792-2582

How Supplied: 2 fl. oz. (60ml) non-aerosol pump spray.

Storage: Keep container closed (capped) when not in use. Store away from excessive heat or cold.

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



FUNGICURE INTENSIVE

clotrimazole liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52389-600	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:52389- 600-60	1 in 1 BOX	06/05/2008		
1		60 mL in 1 BOTTLE, SPRAY; 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	06/05/2008		

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

Revised: 11/2023 Alva-Amco Pharmacal Companies, Inc.