

FUNGICURE INTENSIVE- clotrimazole liquid

Alva-Amco Pharmacial Companies, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredient

Clotrimazole 1% w/v

Purpose

Antifungal

Uses

For the cure of most:

- athlete's foot (tinea pedis)
- ringworm (tinea corporis)
- 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 using.
- 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 of the 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; for jock itch, use daily for 2 weeks.
- 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 cuticles, around nail edges and under nail tips. While not all finger and toe 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

Isopropyl alcohol

Questions? 1-800-792-2582

Product Insert

FUNGICURE INTENSIVE

Broad Spectrum Anti-Fungal Treatment

Cures Finger and Toe Area Fungal Infections

- Instant Dry
- No Odor
- No Mess

A WORD ABOUT FUNGICURE INTENSIVE PUMP SPRAY LIQUID:

FUNGICURE INTENSIVE Anti-Fungal Pump Spray Liquid is strong medicine for the treatment of common fungus infections of the body, hands and feet including the finger and toe areas. Fungicure Intensive contains a broad spectrum anti-fungal which eliminates 6 types of fungus including *T. rubrum*, *E. floccosum*, *T. mentagrophytes*, *M. canis*, *M. gypseum* and *T. tonsurans*. Rely on FUNGICURE INTENSIVE for the cure of most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris). FUNGICURE INTENSIVE Pump Spray Liquid is crystal clear, odorless, and applies easily with its non-aerosol pump spray, delivering highly effective anti-fungal medication directly to the site of infection. With FUNGICURE INTENSIVE Pump Spray, fingers need never touch affected areas.

WHAT IS FUNGUS INFECTION?

Generally speaking, common fungus infections are topical infections caused by a variety of fungi; actual living organisms (members of the yeast and mold family) which exist in the natural environment and tend to thrive in dark, damp conditions. These organisms may penetrate the skin's surface through even the smallest crack or tear and may be contracted by touching infected surfaces, animals or other people. Once infection starts, spreading may occur among body parts...from toe to toe...from finger to finger.

Common topical fungi infectives generally fall into three categories: microsporum (hair and skin), epidermophyton (skin and nails), and trichophyton (hair, skin and nails). Among the more common fungi is *E. floccosum*, which can cause ringworm infection on the body, hands and feet, on and in between the fingers and toes including the skin around the nails. Other common fungi are *T. rubrum* and *T. mentagrophytes*, which can cause athlete's foot and infect the feet on and between the toes including the skin around the toenails. Often such infections develop slowly and may be difficult to treat if not attended to promptly with an effective anti-fungal medicine.

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, commonly referred to as ringworm. Other such infections, 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, friable (easily broken) and in some cases, discolored (greenish/brown). NOTE: If you believe you may have any type of fungus infection, do not delay consulting a doctor for advice. You may wish to show him/her FUNGICURE INTENSIVE Pump Spray Liquid and discuss its use.

HOW FUNGICURE INTENSIVE PUMP SPRAY LIQUID ANTI-FUNGAL WORKS; PRODUCT DESCRIPTION AND ACTION:

FUNGICURE INTENSIVE Pump Spray Liquid is an effective topical formulation containing the ACTIVE INGREDIENT: Clotrimazole 1% w/v. INACTIVE INGREDIENT: Isopropyl alcohol. The active ingredient Clotrimazole in FUNGICURE INTENSIVE is a widely recognized, doctor recommended anti-fungal agent effective against fungi such as *E. floccosum*, *T. mentagrophytes* and *T. rubrum*, which are known to cause topical infections of the body, hands and feet. FUNGICURE INTENSIVE Pump Spray eliminates and helps stop the spread of fungal infection where reachable with its medicated spray liquid. FUNGICURE INTENSIVE helps soothe and relieve itching, scaling, cracking, burning, redness, soreness, irritation and discomforts which may accompany fungus infection by eliminating the fungus...allowing for the natural regrowth of healthy skin.

PROMPT ACTION AND PROPER TREATMENT:

Recognizing and treating fungus infection early is very important for successful results, so it is wise to consult your doctor promptly for advice if you suspect you may have a fungal infection. It is likewise important for successful results that once treatment is started with FUNGICURE INTENSIVE, it is continued uninterrupted, carefully following and adhering to package directions until satisfactory results are achieved or with further advice from a doctor. Factors such as product odor and ease of use are important in the encouragement of proper and continued use. Therefore FUNGICURE INTENSIVE Pump Spray Liquid is formulated to be easy to apply, fast drying, odorless and crystal clear. NOTE: Noticeable improvement may be expected within 4 weeks in the case of athlete's foot (*tinea pedis*) and ringworm (*tinea corporis*), two weeks for jock itch (*tinea cruris*). Consult your doctor for advice if noticeable improvement is not evident by this time or if condition persists or worsens.

HOW CAN YOU AVOID RECURRENCE OF FUNGUS INFECTION?

1. Keep hands and feet meticulously clean and dry, as well as any areas of the body that may be normally covered by clothing that restricts air flow allowing moisture to build up. Fungus enjoys and thrives on moisture. Good personal hygiene is your first line of defense against recurring fungus infections.
2. In cases where athlete's foot (*tinea pedis*) has been a problem, wear well-ventilated shoes, and change shoes and socks daily.
3. Avoid trimming cuticles and avoid cutting nails too close. Anything that tears or opens the skin invites fungus to invade. Be very observant for early signs of recurrence and don't hesitate to take prompt action with FUNGICURE INTENSIVE Pump Spray Liquid following package directions carefully.

Uses: For the cure of most: athlete's foot (*tinea pedis*), ringworm (*tinea corporis*), jock itch (*tinea*

cruris). 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 (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 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; for jock itch, use daily for 2 weeks. 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: FUNGICURE INTENSIVE spray may be applied to 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 until satisfactory results are obtained. You may report serious side effects to the phone number provided under Questions? below.

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.

100-6R,
0412

Fungi CURE[®]

INTENSIVE

**BROAD SPECTRUM
Kills 6 Types of Fungus**

Fungi CURE[®]

INTENSIVE

ANTI-FUNGAL TREATMENT

**Cures
Finger & Toe
Area Fungal
Infections**

• Instant Dry
• No Odor
• No Mess

Easy Pump Spray

Works Upside Down

Topical Formula
Net Contents 2 fl. oz. (60 ml)

Topical Formula

Dist.: ALVA-AMCO Pharmaceutical Cos., Inc.
Niles, IL 60714, U.S.A.
© 2007-2012 ALVA
® Reg. U.S. Patent and Trademark Office

Lot No.:
Exp.:

Prod. No. 1000060



0 72959 01000 3
PROOF OF PURCHASE

3



FUNGICURE[®]
THE FINGER & TOE
FUNGI SPECIALIST[®]

For healthy looking
fingers & toes



Kills fungus where
reachable with medicated
spray liquid. Nothing stronger
without a prescription.

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KEEP CONTAINER CLOSED (CAPPED)
WHEN NOT IN USE. STORE AWAY FROM
EXCESSIVE HEAT AND COLD.

FUNGICURE[®]
INTENSIVE

Anti-Fungal Liquid
Pump Spray

FUNGICURE INTENSIVE is highly effective in killing fungus on fingers and toes including areas around nails where reachable with its medicated anti-fungal spray liquid.

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

Drug Facts	
Active ingredient	Purpose
Clotrimazole 1% w/v	Antifungal
Uses For the cure of most: ■ athlete's foot (tinea pedis) ■ ringworm (tinea corporis) ■ jock itch (tinea cruris). For relief of: ■ itching ■ scaling ■ cracking ■ burning ■ redness ■ soreness ■ irritation ■ discomforts which may accompany these conditions.	
Warnings	
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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 using. ■ 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 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; for jock itch, use daily for 2 weeks. ■ 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.	
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Inactive ingredient	
Isopropyl alcohol	
Questions? 1-800-792-2582	

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
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Isopropyl alcohol (UNII: ND2M416302)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52389-600-60	1 in 1 BOX		
1		60 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	06/05/2008	

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

Revised: 1/2013

Alva-Amco Pharmacial Companies, Inc.