

FUNGICURE MANICURE PEDICURE ANTI FUNGAL- clotrimazole liquid
Denison Pharmaceuticals, LLC

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.

Fungicure Manicure Pedicure Anti Fungal Liquid

Active ingredient

Clotrimazole 1% w/v.

Purpose

Antifungal

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

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

Inactive ingredient

Isopropyl alcohol

Directions

- Read and all package directions and warnings before using.
- Use only as directed.
- Clean the affected area with soap with warm water and dry thoroughly.
- Apply a thin layer of FUNGICURE Manicure & Pedicure Liquid 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. 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

- FUNGICURE may be applied to 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

Questions? 1-800-792-2582

Maximum Strength
FUNGI CURE[®]
Manicure & Pedicure
Professional Formula

ANTI-FUNGAL TREATMENT

Net Contents 1 fl.oz. (30ml)

Active ingredient: Clotrimazole 1% w/v **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 Manicure & Pedicure Professional Formula 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. 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:** FUNGICURE may be applied to 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 Ingredient:** Isopropyl alcohol. **Questions?** 1-800-792-2582

unvarnished area

ALVA-AMCO Pharmaceutical Cos., Inc.
Niles, IL 60714, U.S.A.
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Fungicure Manicure & Pedicure (60-8R) Drug Facts

Drug Facts	
Active ingredient Clotrimazole 1% w/v	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 using ■ Use only as directed ■ Clean the affected area with soap and warm water and dry thoroughly. ■ Apply a thin layer of FUNGICURE Manicure & Pedicure Liquid 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. 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.	
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Inactive ingredient Isopropyl alcohol	
Questions? 1-800-792-2582	

FUNGICURE MANICURE PEDICURE ANTI FUNGAL

clotrimazole liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0295-6307
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength

ISOPROPYL ALCOHOL (UNII: ND2M416302)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0295-6307-05	30 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	12/12/2018	
2	NDC:0295-6307-44	60 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	12/12/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/12/2018	

Labeler - Denison Pharmaceuticals, LLC (001207208)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	manufacture(0295-6307)

Revised: 1/2019

Denison Pharmaceuticals, LLC