

FUNGINIX ANTI-FUNGAL TREATMENT- undecylenic acid ointment
The Sisquoc Healthcare Corporation

Sisquoc HC (as PLD) - FUNGINIX ANTI-FUNGAL TREATMENT (71229-102)

ACTIVE INGREDIENT

UNDECYLENIC ACID 10%

PURPOSE

ANTIFUNGAL

USES

- ANTI-FUNGAL TREATMENT

WARNINGS

FOR EXTERNAL USE ONLY.

DO NOT USE ON CHILDREN UNDER 2 YEARS OF AGE UNLESS DIRECTED BY A DOCTOR.

WHEN USING THIS PRODUCT AVOID CONTACT WITH THE EYES. IF CONTACT OCCURS, RINSE THE EYES VERY THOROUGHLY WITH WATER.

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

- 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.
- Clean the affected area with soap and warm water and dry thoroughly. Apply a thin layer of FUNGINIX over the affected area twice daily (morning and night), or as directed by a physician. Allow 3-5 minutes for the solution to penetrate the skin and absorb fully into the surrounding tissue.
- FUNGINIX should be applied to cuticles, around nail edges and under nail tips where reachable with the applicator brush. This product is not intended to, nor will it, penetrate hard nail surfaces.
- 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.

INACTIVE INGREDIENTS

Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Oleth-10 Phosphate, Triethanolamine, Polysorbate 20, Acrylates Copolymer, Glycerin, Propylene Glycol, Uva Ursi (Bearberry) Extract, Beta-Glucan, Propolis Extract, Aloe Barbadensis Juice, Tocopheryl Acetate (Vitamin E), Camphor, Menthol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Lavandula Angustifolia (Lavender) Oil, Jasminum Officinale (Jasmine Oil), Eugenia Caryophyllus (Clove) Flower Oil, Theobroma Cacao (Cocoa) Seed Butter, Rosa Canina (Rose Hip) Flower Oil, Cetyl Hydroxyethylcellulose, Ethylhexylglycerin, Phenoxyethanol

Store between 20°C to 25°C (68° to 77°F)

Active Ingredient: Undecylenic Acid 10%

Warnings

For external use only. Do not use on children under 2 years of age unless directed by a doctor. **When using this product,** avoid contact with the eyes. If contact occurs, rinse the eyes very thoroughly with water.

Stop use and ask a physician if irritation occurs or if there is no improvement within 4 weeks. **Keep out of the reach of young children.** If swallowed, get medical assistance or contact a poison control center.

MAXIMUM STRENGTH

FUNGINIX

ANTI-FUNGAL TREATMENT

1 FL OZ / 30 ML

Directions

Shake well before using. Wash affected area and dry thoroughly. Apply a full brush application to the affected area (around the nail underneath nail tips) twice daily. Allow product to absorb into the surrounding skin for 3-4 minutes.

Read the included information sheet for complete Drug Facts.

Distributed by:
Sisquoc Healthcare, Inc.
Newport Beach, CA 92660 U.S.A.
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Maximum Strength

FUNGINIX

Anti-Fungal Treatment

Kills the fungus on fingers and toes that infect healthy nails and cause fungal infections.

WHAT IS A TOPICAL FUNGUS INFECTION?

Common topical fungus infections of the fingers and toes are caused by different types of fungi. These living organisms thrive in dark, moist conditions. The fungi cause infections by finding small imperfections or breaches in the skin. Once the infection sets in, it can easily

HOW LONG SHOULD TREATMENT LAST?

Treatment periods depend on the severity of the infection. For mild to medium fungal infections, treatment should be no less than 3 months. Fungal infections are stubborn and will often return if the treatment is not thorough enough to eliminate all fungal agents in and around the infection. Medium to severe infections may require between 6-12 months of treatment before the infection is eliminated. If no tangible improvement in the infection is seen within 4 weeks, consult a physician.

DIRECTIONS:

○ 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.

spread to the nails. For example, infected fingers and toes can infect other fingers and toes. These infections can be difficult to eliminate if they are given time to settle in and live peacefully. Therefore, it is important to begin treatment immediately with FUNGINIX anti-fungal treatment.

Topical fungus infections come in many forms. For instance, certain fungal infections form on the surface of the skin and create irritated skin in the shape of a ring. This condition is referred to as ringworm. Athlete's foot fungus is generally found around fingers or toes and presents itself as skin that is extremely dry, cracking, burning or itching. When nails become infected with fungus, they will often become cloudy, thickened, brittle and sometimes quite discolored.

Fungal infections of the nail areas are often caused by the same fungi that lead to athlete's foot and ringworm infections on other parts of the body. These fungi can infect the entire area around the nails including the cuticle, nail beds and nails themselves. When finger or toenails are infected, FUNGINIX acts quickly to eliminate the fungal infection at the site of the infection.

WHY USE FUNGINIX ANTI-FUNGAL TREATMENT?

Maximum Strength FUNGINIX anti-fungal treatment contains Undecylenic Acid, 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. gypsum*, *T. tonsurans* and *T. rubrum*.

When applied as directed, FUNGINIX anti-fungal treatment acts promptly to target, destroy and prevent the spread of infection by inhibiting the growth and reproduction of fungal cells. Early treatment of fungal infections is important. If you suspect that you may have a fungal infection, consult your physician promptly for advice and proper diagnosis. You may wish to show your physician FUNGINIX anti-fungal treatment and discuss its use. Once treatment is started with FUNGINIX anti-fungal treatment, it is important to follow the treatment instructions in order to achieve the best possible results in the shortest amount of time.

○ Clean the affected area with soap and warm water and dry thoroughly. Apply a thin layer of FUNGINIX over the affected area twice daily (morning and night), or as directed by a physician. Allow 3-5 minutes for the solution to penetrate the skin and absorb fully into the surrounding tissue.

○ FUNGINIX should be applied to cuticles, around nail edges and under nail tips where reachable with the applicator brush. This product is not intended to, nor will it, penetrate hard nail surfaces.

○ 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.

WARNINGS:

○ Use only as directed. For external use only.

○ Ask a doctor before using on children under 2 years of age.

○ When using this product avoid contact with eyes.

○ Stop using and ask a physician 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

Active Ingredient: *Undecylenic Acid (10%)*

Inactive Ingredients: Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Oleth-10 Phosphate, Triethanolamine, Polysorbate 20, Acrylates Copolymer, Glycerin, Propylene Glycol, Uva Ursi (Bearberry) Extract, Beta-Glucan, Propolis Extract, Aloe Barbadosis Juice, Theophylline Acetate (Vitamin E), Camphor, Menthol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Lavandula Angustifolia (Lavender) Oil, Jasminum Officinale (Jasmine) Oil, Eugenia Caryophyllus (Clove) Flower Oil, Theobroma Cacao (Cocoa) Seed Butter, Rosa Canina (Rose Hip) Flower Oil, Cetyl Hydroxyethylcellulose, Ethylhexylglycerin, Phenylethanol

This product has not been evaluated by the FDA. FUNGINIX is not intended to treat, diagnose, cure or prevent any disease.



Sisquoc Healthcare, Inc.



Newport Beach, CA 92660 USA
Questions? (800) 589-8913

FUNGINIX ANTI-FUNGAL TREATMENT

undecylenic acid ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71229-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALMOND OIL (UNII: 66YXD4DKO9)	
OLETH-10 PHOSPHATE (UNII: Q95361F4VS)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARCTOSTAPHYLOS UVA-URSI WHOLE (UNII: 37SXO36KR7)	
OAT (UNII: Z6J799EAJK)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAMPHOR OIL (UNII: 75IZZ8Y727)	
MENTHOL (UNII: L7T10EIP3A)	
TEA TREE OIL (UNII: VIF565UC2G)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
JASMINUM OFFICINALE WHOLE (UNII: X3314B4SYD)	
CLOVE OIL (UNII: 578389D6D0)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ROSA CANINA FLOWER OIL (UNII: DUY7M48I1T)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71229-102-11	30 mL in 1 TUBE; Type 0: Not a Combination Product	03/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	03/25/2019	

Labeler - The Sisquoc Healthcare Corporation (021517142)

Revised: 10/2023

The Sisquoc Healthcare Corporation