

FUNGINIX AF- tolnaftate cream
The Sisquoc Healthcare Corporation

Sisquoc HC (as PLD) - FUNGINIX AF ATHLETE'S FOOT CREAM (71229-103)

ACTIVE INGREDIENT

TOLNAFTATE 1%

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 all forms of athlete's foot (tinea pedis). For relief of itching, scaling, cracking, burning, redness, soreness, irritation and discomforts which may accompany these conditions.
- Wash affected area and dry thoroughly. Apply a layer of FUNGINIX AF over the affected area twice daily (morning and night). Allow the cream to dry for at least 3 minutes before covering the affected area with clothing.
- Wash hands after each application to prevent the chance of the infection spreading to other parts of the skin.
- Most athlete's foot infections will require at least 2 weeks of continuous daily treatment before the infection is completely eliminated.
- Proper use of FUNGINIX AF should eliminate all types of athlete's foot infections. If the condition persists longer, contact a physician or medical professional.

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)

MAXIMUM STRENGTH

FUNGINIX AF

ATHLETE'S FOOT CREAM

1 OZ / 28 G

Active Ingredient: Tolnaftate 1%

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 eyes. If contact occurs, rinse eyes thoroughly with water.

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

Directions: Wash affected area and dry thoroughly before applying. Apply cream twice daily (morning and night) for 2 weeks or as directed by a doctor. Allow cream to dry before applying socks and/or shoes. Wear well-fitting, ventilated shoes. Change socks at least once daily.

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

Distributed By: Slsquoc Healthcare, Inc. Newport Beach, CA 92660 U.S.A. © 2017

Maximum Strength

FUNGINIX AF

**HOW LONG SHOULD
TREATMENT LAST?**

Athlete's foot infections should be treated the moment the infection is detected. The earlier you begin treating the infected areas.

Athlete's Foot Cream

Specifically designed to swiftly eliminate athlete's foot infections.

WHAT IS ATHLETE'S FOOT?

Athlete's foot, known medically as tinea pedis, is a common skin infection of the feet caused by fungus. Signs and symptoms often include itching, scaling, and redness. In severe cases the skin may blister. Athlete's foot fungus may infect any part of the foot, but most often grows between the toes. The next most common area is the bottom of the foot. The same fungus may also affect the nails or hands. It is a member of the group of diseases known as tinea.

Tinea pedis is caused by a number of different fungi. The condition is typically acquired by coming into contact with infected skin, or fungus in the environment. Common places where the fungi can survive are around swimming pools and in locker rooms. They may also be spread from other animals. Usually diagnosis is made based on signs and symptoms.

Some methods of prevention include avoiding walking barefoot in public showers, keeping the toenails short, wearing big enough shoes, and changing socks daily. When infected, the feet should be kept dry and clean and wearing open-toed shoes can help. Treatment can be either with an antifungal medication like **FUNGINIX AF** which is applied to the skin such as tolnaftate or for persistent infections antifungal medication that are taken by mouth such as terbinafine. Use of any antifungal cream is typically recommended for a minimum of four weeks.

WHY USE FUNGINIX AF TO ELIMINATE ATHLETE'S FOOT?

FUNGINIX AF is an excellent combination of anti-fungal agents, essential oils and fungus-fighting extracts specifically created to fight athlete's foot. In order to create the most powerful anti-fungal solution, we at Sisquoc Healthcare took the best of research from both traditional and herbal medicine on how to kill the fungi responsible for athlete's foot infections. After comparing and contrasting the effects

of various combinations we came up with **FUNGINIX AF**. The shorter the treatment period will be. Once treatment with **FUNGINIX AF** begins, it should be uninterrupted for a minimum of 2 weeks. More severe treatments may require up to 4-6 months to eliminate all existing fungal agents. It is **VERY IMPORTANT** to continue treatment beyond the time when the infection is no longer visible. All fungal infections, like athlete's foot, often return if the treatment period is not thorough enough to kill **ALL** of the fungal agents, not just those visible. In stubborn cases if substantial progress is not by then, a medical professional should be consulted to discuss alternative methods of treatment.

DIRECTIONS:

- ✦ For the cure of all forms of athlete's foot (tinea pedis). For relief of itching, scaling, cracking, burning, redness, soreness, irritation and discomforts which may accompany these conditions.
- ✦ Wash affected area and dry thoroughly. Apply a layer of **FUNGINIX AF** over the affected area twice daily (morning and night). Allow the cream to dry for at least 3 minutes before covering the affected area with clothing.
- ✦ Wash hands after each application to prevent the chance of the infection spreading to other parts of the skin.
- ✦ Most athlete's foot infections will require at least 2 weeks of continuous daily treatment before the infection is completely eliminated.
- ✦ Proper use of **FUNGINIX AF** should eliminate all types of athlete's foot infections. If the condition persists longer, contact a physician or medical professional.

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 consult a physician if the condition continues and 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: Tolnaftate (1%)

Inactive Ingredients: Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Oleth-10 Phosphate, Trietha-

or various combinations, we came up with our unique blend of active ingredients like Tolnaftate, herbal remedies like camphor and essential oils like tea tree oil. There is simply no other topical toenail fungus treatment created to fight athlete's foot that is more effective and complete.

nolamine, 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

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



Sisquoc Healthcare, Inc.
 Newport Beach, CA 92660 USA
 Questions? (800) 589-8913

FUNGINIX AF

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71229-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALMOND OIL (UNII: 66YXD4DKO9)	
OLETH-10 PHOSPHATE (UNII: Q95361F4VS)	
TROLAMINE (UNII: 903K93S3TK)	
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)
THEOBROMA CACAO WHOLE (UNII: EB048G1S9J)
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)
CAMPHOR OIL (UNII: 75IZZ8Y727)
MENTHOL (UNII: L7T10EIP3A)
TEA TREE OIL (UNII: VIF565UC2G)
LAVANDULA ANGUSTIFOLIA WHOLE (UNII: 51217XIL5L)
JASMINUM OFFICINALE WHOLE (UNII: X3314B4SYD)
CLOVE LEAF OIL (UNII: VCA5491KVF)
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:71229-103-11	28 g 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